Food·Drug·Cosmetic Law

The editorial policy of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need.

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FOOD DRUG COSMETIC LAW JOURNAL

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REPORTS

TO THE READER

About the Authors

Presently Chief of Boston District, Food and Drug Administration, **F. Leslie Hart** entered the Bureau of Chemistry at Washington, D. C., in 1920. After functions of that bureau were transferred to the newly established Food and Drug Administration in 1927, he served in Chicago and St. Louis Stations of the Administration, later spending three years in the Washington laboratories as research chemist. Mr. Hart was appointed chief chemist of Buffalo Station in 1934, and went to Los Angeles as chief chemist of that district in 1937. He became Chief of Boston District last year.

He was born in Pennsylvania, and received his education there (B. S. and M. S., Dickinson College, Carlisle). In addition to his career in government service, Mr. Hart has authored some 30 papers on analysis of food and drugs, most of them published in the *Journal of the Association of Official Agricultural Chemists;* he has been a referee for many years on "detection of gums in foods," for that organization; he is past chairman of the Southern California Section of the Institute of Food Technologists; and he is a member of the advisory committee of Chemical and Engineering News Service, American Chemical Society.

Burton R. Rissman received his B. S. degree in civil engineering from the University of Illinois in 1947, and a degree of J. D. from the same university in 1951. He served with the board of student editors of the *University of Illinois Law Forum.* Mr. Rissman, who was a 1951-1952 fellow in the Food Law Institute's program at New York University School of Law, is a member of the Illinois Bar and the Illinois State Bar Association; of the Order of the Coif; and of Phi Delta Phi legal fraternity.

Edwin L. Harding, counsel for the Kellogg Company for over 14 years, is a member of the Michigan, the District of Columbia and the Illinois bars, and of the Lawyers' Advisory Committee, Food Law Institute, Inc.

RE: DELANEY COMMITTEE REPORT

The Delaney Committee's cosmetic report supplements the food report and has an equivalent significance. This report on the similar cosmetic chemical pretesting amendment will be included in the FOOD DRUG COSMETIC LAW JOURNAL for September.

In Congress

INVESTIGATION OF THE USE OF CHEMICALS IN FOODS AND COSMETICS

Report by Delaney Committee on Food Chemical Pretesting Amendment to Federal Food, Drug, and Cosmetic Act—Food

82D CONGRESS, *2d Session*
HOUSE OF REPRESENTATIVES
REPORT No. 2356

JUNE 30, 1952—COMMITTED TO THE COMMITTEE OF THE WHOLE HOUSE ON THE STATE OF THE UNION AND ORDERED TO BE PRINTED

Mr. DELANEY, from the Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics, submitted the following

REPORT

[Pursuant to H. Res. 74, 82nd Cong., 1st sess.]

FOOD

I. Introduction

The Select Committee to Investigate the Use of Chemicals in Food Products was created under the provisions of House Resolution 323 (81st Cong., 1st sess.), agreed to June 20, 1950. The resolution authorized and directed your committee to conduct a full and complete investigation of—

"1. The nature, extent, and effect of the use of chemicals, compounds, and synthetics in the production, processing, preparation, and packaging of food products to determine the effect of the use of such chemicals, compounds, and synthetics (A) upon the health and welfare of the Nation, and (B) upon the stability and well-being of our agricultural economy;

"2. The nature, extent, and effect of the use of pesticides and insecticides with respect to food and food products, particularly the effect of such use of pesticides and insecticides upon the health and welfare of the consumer by reason of toxic residues remaining on such food and food products as a result of such use; and

"3. The nature, effect, and extent of the use of chemicals, compounds, and synthetics in the manufacture of fertilizer, particularly the effect of such use of chemicals, compounds, and synthetics upon (A) the condition of the soil as a result of the use of such fertilizer, (B) the quantity and quality of the vegetation growing from such soil, (C) the health of animals consuming such vegetation, (D) the quantity and quality of food produced from such soil, and (E) the public health and welfare generally."

The committee was appointed by the Speaker of the House on July 20, 1950. House Resolution 739, agreed to August 21, 1950, appropriated $30,000 from the contingent fund of the House to finance the investigation. Public hearings were held during the months of September, November, and December, 1950. Twenty days were devoted to these hearings, in which 74 witnesses were heard.

On January 3, 1951, the committee submitted its report (H. Rept. 3254, 81st Cong., 2d sess.), which summarized the testimony presented to it and recommended that further study and investigation be undertaken before final conclusions were reached. At the close of the Eighty-first Congress, the committee had expended $13,181.43 of the $30,000 appropriated for its investigation. The unexpended balance of $16,818.57 was returned to the contingent fund of the House. Of the sum expended, $3,668.46 were paid to

(Continued on page 519)

Vol. 7, No. 8 August, 1952

Food·Drug·Cosmetic Law Journal

Food Adulteration in the Early Twentieth Century

By F. LESLIE HART

Protection of the Nation's Food Supply Received Effective Legislative Attention at the Beginning of the Century. This Article Continues the History of Adulteration and Remedial Legislation Begun by the Author in January's JOURNAL

**"Things are seldom what they seem,
Skim milk masquerades as cream."—*HMS PINAFORE***

AN earlier article [1] traced the history of food adulteration from the beginning of commerce in foods to the enactment of the Federal Food and Drugs Act in 1906. This article will continue the story.

The nineteenth century had brought about an increased awareness by the peoples and governments of the world of the existence of purposeful adulteration of foods. Books and articles had been published—some factual, others polemic. The era from 1870 to 1900 or so had seen most of the major countries enact comprehensive general laws designed to control the evil. The first few years of the new century saw a reappraisal of the effectiveness of these laws by the legislatures, or by the bodies administering the laws. In many cases, revisions of law followed. Portugal and Denmark revised existing laws in 1903. France, in 1905, enacted a very comprehensive law, retaining some of the features of earlier laws, but broadening the definition of "adulteration" and stiffening the penalties. Imprisonment was

[1] 7 FOOD DRUG COSMETIC LAW JOURNAL 5 (1952).

The Author is Chief, Boston District, Food and Drug Administration, Federal Security Agency

made obligatory for certain offenses. In the same year, Switzerland enacted a law which exercised control through the cantons, under general direction of the central government.

By an odd coincidence, both the United States and Great Britain appointed commissions around 1900 to investigate the purity of their food supplies. Congress, in 1898, by law established "The Industrial Commission on Agriculture and Agricultural Labor." This body was instructed "to investigate questions pertaining to emigration, to labor, to agriculture, and to business, and to report to Congress, and to suggest such legislation as it may seem best . . . ." The commission issued voluminous reports on many subjects including, in Volumes X and XI, released in 1901, a conclusion that there was a definite demand for national pure food legislation.

The British commission, called "The Departmental Committee Appointed to Inquire into the Use of Preservatives and Coloring Matters in Foods," was established in 1899 and reported in 1901.[2] This group estimated that 50 per cent of the dairymen of London used preservatives (in milk, cream or butter). They concluded there was little justification for the use of preservatives in milk, since, with proper organization of the milk suppliers, milk could and should be speedily delivered. It observed that other countries, such as Denmark, strictly prohibited the use of preservatives in dairy products. However, they added that there may be some justification for their use in cream, since it is consumed in smaller amounts. The report suggested that cream be labeled to show the presence of a preservative "so as to protect invalids and children." This committee recommended that for-

[2] Thresh and Porter, *Preservatives in Food and Food Examination*, p. 431 (1906).

maldehyde be banned; that salicylic acid be limited to one grain per pound of food, its presence to be declared; and that boric acid in food be limited to 0.5 per cent.

Congress, either by the Senate or House, held several Congressional hearings on the need of pure food legislation. A witness at one of these hearings related an amusing story of the grocer who called down from the second floor, where he lived with his family: "Boy, have you watered the oysters?" "Yes," said his apprentice. "Have you mixed the tea?" "Yes." "Well, then," called the grocer, "come up and say prayers with us."

In this country, many of the states passed food laws during the period between 1875 and 1900. This naturally led to an intensified campaign for a federal law. Books were written, orations given—some quite intemperate in language—bewailing the evils brought about by the practice of adulterating the Nation's food supply. An example or so will show the temper of the times. A pamphlet published in Philadelphia in 1885 included an address by a Mr. H. Wharton Amerling.[3] Said he:

> He who with the bloody, black hand of adulteration quickens the pulse, parches the lip, blinds the eye, paralyzes the hand, foot and tongue, at length is a fiend more merciless than Caligula, Nero, or the slayer of the innocents. The infamy of Satan is virtue compared to such perfidy!

This speaker implied that adulteration of food causes an increase in lunacy. A member of the Forty-eighth Congress, Hon. J. Wharton Green, called adulteration "a crying evil, a monstrous crime." He suggested the penalty of "boiling in oil," and said that philanthropists should advocate "purity, not prohibition." An instructor at Massachusetts Institute of Technology wrote[4] that "wholesome and palatable food is the first step in good morals, and is conducive to ability in business, skill in trade, and healthy tone in literature."

A law regulating the importation of foods was enacted in 1890. Dr. Harvey W. Wiley and others led a well-organized crusade that culminated in the enactment by Congress of the Federal Food and Drugs Act of 1906. By this time, the food business had become quite competitive and economic cheats were common. One state enforcement official estimated that two thirds of our spices, one half our olive oil, 40 per cent of the commercial milk and butter supply, half of the

[3] *Address of H. Wharton Amerling upon the Formation of the American Society for the Prevention of Adulteration of Foods, Drugs, etc.* (1885).

[4] Mitchell, Ellen H., *Food Materials and Their Adulteration*, p. 7 (1886).

ice cream, and a quarter of the honey was debased with diluents or otherwise adulterated. Another midwest state reported that there was three times as much maple sugar and maple syrup sold under the name "pure Vermont" in his state as could be produced by all the sugar maple trees in the entire country. Half the 4,193 food samples examined as late as 1910 by Minnesota State chemists were illegal, as disclosed by that state's annual report.

Bigelow, Chief of the Division of Foods, United States Bureau of Chemistry,[5] tabulated reports made by state chemists on the purity of their milk supplies. These show that a big proportion of the milk sold was either skimmed or watered, artificial color being added to conceal the fraud.

"Cow with the Iron Tail"

A. L. Winton once described this practice as "milking the cow with the iron tail." In fact, one state, Minnesota, reported in 1901 that all the milk examined was adulterated. Lythgoe[6] reported in 1900 that in Massachusetts 48 per cent of the milk samples examined by the state laboratories contained aniline orange, a coal-tar dye. He also reported frequent use of formaldehyde as a preservative. In 1902, that state examined 5,870 samples of milk. Thirty per cent were found to be adulterated. New Hampshire in 1903 reported the same percentage; Ohio reported 25 per cent, but Minnesota again led with 80 per cent. With the passage of the 1906 law, and increased attention by state and city officials, sophistication of milk lessened, but did not vanish.

The Annual Report of the Chemist, United States Department of Agriculture, 1909, recorded that market milk of Cincinnati was well-watered, 60 per cent of the samples being thus adulterated. There the dairies ventured the ingenuous excuse that they did add ice to the milk but only to cool it, not dilute it! Doctor Wiley, the chemist, commented: "While the use of ice for cooling milk, if applied the right way, is most commendable, the addition of it to milk itself is not to be tolerated."

The 1910 report describes a survey by the Boston Laboratory of the Bureau of Chemistry of the interstate milk arriving at Boston and Springfield, Massachusetts. They report that 13 per cent of the samples were illegal.

[5] *Bureau of Chemistry Bulletin 100* (1906).

[6] 22 *Journal of the American Chemical Society* 813 (1900).

Canada had, several years earlier, reported better conditions in general. Out of 224 samples tested in 1903-1904, 15 were watered and eight were skimmed. No mention was made of artificial color.

It has been reported that about this time in London coloring of milk was so common that housewives refused to buy the uncolored product, thinking *it* was adulterated. This arose from the fact that the natural color of milk is almost white, with just a touch of yellow, while skimmed or diluted milk has a bluish cast. To hide this, London milkmen would add a little yellow color. Gradually all the milk in the city, whether diluted or not, was artificially colored. The buyer, considering this yellowish tinge to be the hallmark of quality, refused to buy the natural milk. Not until 1925 did British law forbid adding color to milk.

The director of the Paris Municipal Laboratory, describing the milk supply of that city around 1900, attributed [7] the first fraud to the farmer, who skimmed off some of the rich top-milk. The next dilution or skimming took place at the receiving stations of the dairy companies. The cans, duly sealed, started for Paris. There they were picked up by the drivers of the retail delivery wagons. They again diluted the milk before starting on their rounds. It was reported that these drivers tripled their wages by this practice. From this money they contributed $4 a week to a fund to pay for legal defense for any drivers caught, and to pay double wages to any drivers while in jail. The article quoted said there were 800 drivers in Paris. Thus a fund of $3,200 a week was maintained.

Adulteration of Tea and Coffee

It is interesting to contrast adulteration of the two table beverages, tea and coffee, in the era just preceding enactment of the federal 1906 Act. This country had enacted an "Adulterated Tea Act" as early as 1883. Bigelow, in the Bureau of Chemistry bulletin previously mentioned,[8] states that "it is believed that no adulterated tea comes into this country, and it is probably true that adulteration is not practiced after entry." As to coffee, he believed that while the green coffee is unadulterated at the time of entry, adulteration after it reaches our shore "is not uncommon." A magazine report [9] stated that there were at least six firms in the United States regularly engaged in the manufacture of machinery to make artificial coffee beans. These

[7] 32 *Current Literature* 399 (1902).
[8] Footnote 5.
[9] 7 *World's Work* 4377 (1904). See also 65 *Scientific American* 321 (1891).

made beans from cereals and other vegetables so cleverly that, after roasting, they were "better looking than the bush-grown berry." It was stated there were hundreds of these machines in operation. Ground roasted coffee, according to Bigelow, was frequently cheapened with chicory, but also other roasted vegetable products, such as peas, wheat, barley and beans, were in use. (This was around 1900.) Again, through a tabulation of state records, it is reported that 20 per cent of the 641 samples examined contained roasted seeds other than coffee. Ohio seemed to be the worst offender, two thirds of the samples examined by the Ohio Dairy and Food Commission in 1901-1902 being so adulterated. In contrast, in Massachusetts, in 1905, only four coffees of 90 examined were adulterated. Bigelow also remarked that the sale of Brazilian coffee for Java or Mocha was very common. One of the early seizures under the 1906 Act was that of 84 sacks of coffee that was colored with lead chromate. In Germany, additional water was concealed in roasted beans by treating the beans with 5 per cent borax solution and redrying. This brought up the moisture content from the usual 4 per cent to 10 or 12 per cent.[10]

Maple Products with Foreign Sugars Added

Maple syrup and maple sugar were easy to adulterate, and official reports show that blenders took advantage of this fact. Senator William E. Mason of Illinois, in a speech to the Senate May 2, 1900, said that testimony before the Senate Committee on Manufacture revealed that the trade had four grades of "maple syrup," ranging from 20 per cent to 80 per cent glucose. A 1910 report from Minnesota states that of 90 maple sugars and maple syrups examined, 23 were mixed with cane sugar. The Kansas Board of Health in 1906 reported that 95 per cent of these maple products examined by them were adulterated. Things were no better in the home of the sugar maple tree—New England and Canada. New Hampshire reported, also in 1906, that only 20 maple syrups of 41 examined were pure maple. The Massachusetts Board of Health found 25 per cent of the 57 maple-product samples adulterated in 1903. Across the border, the Canadian Inland Revenue Laboratory made an extensive survey in 1905 of maple products on retail sale in the Dominion. Two series of samples were collected—one in the early spring, before the season had begun, and the other after the current pack had been processed. In the "off season," their analysts found 76 per cent of the samples were adulterated (with cane sugar or glucose), while

[10] 2 *Pure Products* [Journal] 123 (1906).

only 36 per cent of the samples collected during the summer were thus adulterated. In 1907 the survey was repeated. Fifty-seven out of 257 sugars and 20 of 187 syrups contained a sugar foreign to the maple tree.[11] The percentage of adulteration dropped to 17 per cent, due, it can be presumed, to energetic enforcement campaigns by the Dominion officials. The adulteration of maple products with cane sugar is difficult to control. Canada now examines maple sugars and syrups offered for entry into the United States and issues certificates showing freedom from adulteration.

Butter, Margarine, Jams and Jellies—Incidence of Sophistication

Properly made butter contained somewhat more butterfat around 1900 than it does at present. Laws establishing minimum butterfat contents for butter seem inevitably to standardize the fat content close to the legal minimum. In 1907 Italy required 82 per cent fat; this country 82½ per cent. England's law was based rather on the moisture content, that country setting a maximum of 16 per cent (which meant about 82 per cent butterfat). Germany set the same figure.[12] Early reports show that butters containing 85 to 87 per cent butterfat were not uncommon, in this country or abroad. Remarkable ranges have been reported. Canadian chemists in 1906 reported butters with fat content ranging from 67½ per cent to 94 per cent.[13] Our present standard has been reduced to 80 per cent. Federal and state analysts now rarely find a butter containing 81 per cent or more butter fat.

References are occasionally found reporting the presence of foreign fats in butter. These are practically all brought about through attempts to sell oleomargarine in whole or in part as butter. This actually rarely occurs, except through "bootleg" operations—a main deterrent being the high penalties set for violation of revenue or excise laws. Canada, in 1907, examined 868 samples and only eight, all from Quebec, were found to contain fats foreign to butter.[14] In this country, according to Bigelow,[15] this adulteration was once quite common, but enforcement of state and federal oleomargarine laws has lessened the fraud. He reported what now seem to be fantastic figures, namely: In New Jersey, in 1895, 167 out of 171 samples sold as butter were oleo-

[11] *Canadian Inland Revenue Department Bulletin 120.*

[12] Blyth and Cox, *Foods, Their Composition and Analysis* (7th Ed., 1927).

[13] *Canadian Inland Revenue Department Bulletin 131* (1906).

[14] *Canadian Inland Revenue Department Bulletin 133* (1907).

[15] Footnote 5.

margarine. Pennsylvania in 1900 reported 1033 out of 1777, and Michigan the same year reported 75 of 173 samples to be oleomargarine. Massachusetts, on the other hand, found only nine out of 227 examined in 1899, and 11 out of 177 in 1900.

British food officials, acting under the Sale of Food and Drugs Act of 1906, as quoted in *United States Bureau of Chemistry Bulletin 143*, compared the regulation of margarine factories in England and on the Continent. In Holland, government inspectors could enter into creameries, butter factories and warehouses where butter was made or sold; they could not legally enter margarine factories. In the United Kingdom, inspectors could enter margarine factories but not butter factories. Consequently, Dutchmen who were in the business of adulterating butter called their places margarine factories. Englishmen engaged in adding foreign fats to butter or in mixing margarine and butter put up a sign reading "Butter Made Here," thus keeping out inquisitive inspectors. This defect in the laws of these two countries was corrected by later legislation.

Jams and jellies have always been favorite targets of artful food manufacturers. The addition of coal-tar color, acid and, at times, a synthetic flavor effectively masked the low fruit content. This was particularly true for jelly because visible fruit tissues had been strained off during manufacture. Jams, too, could be debased. One trick occasionally used for berry jams was to throw in a handful of grass seed to simulate the seed of strawberries or raspberries. Another was to add to the jam kettle the exhausted fruit residues obtained from jelly manufacturing. The base of many a jelly was made by boiling in water the apple peel and cores obtained as a by-product of the manufacture of dried apples. Senator William E. Mason, in a speech in the Senate May 2, 1900, told of a trip he had made to a jelly factory. He was shown some beautiful, clear apple jelly and he asked how it was made. The manufacturer said that he boiled up apple parings with glucose, added acid to sour it, and an aniline dye to color it. The senator picked up a glass of currant jelly and said: "How do you make this?" "Just the same as apple jelly," replied the jelly maker, "except that I put in a little more red."

An official government report made in 1902 [16] disclosed that about half the jams and a fourth of the jellies examined by the Bureau of Chemistry were artificially colored. The States reported similar fig-

[16] *Bulletin 66, Bureau of Chemistry, United States Department of Agriculture.*

ures, as quoted by Bigelow.[17] This latter government bulletin also mentions some use, though rare, of saccharin as an artificial sweetener of these products. Minnesota, in 1907, required that imitation jams or jam substitutes, made with corn syrup or glucose as the saccharine ingredient, be labeled: "THIS PREPARATION MIXED AND ADULTERATED." The Canadian Inland Revenue Department examined 74 jams and jellies in 1903-1904. Of these, 55 were listed as adulterated, either through the addition of glucose or the substitution of another fruit (usually apple) for the fruit declared on the label. Canada at this time did not classify the addition of artificial color as an adulteration. The government analyst remarked that several of the samples examined did contain coal-tar dyes. An English author[18] wrote in 1912:

> Some of the commercial jellies are made entirely without fruit. The Director of the Paris Municipal Laboratory found gooseberry jelly which was made entirely of seaweed, colored with aniline dye and flavored with a compound containing acetic ether, succinic acid, tartaric acid, aldehyde and oenanthic acid.

This author also mentions that beetroot and cochineal were used to add red color to jam.

A labeling trick practiced at times was to brand the product "absolutely pure jam" in large type; then, in much smaller type, or hidden elsewhere on the label, would be found the word "compound." Canadian law, and some of the state laws in this country, then permitted this term to a product that later would be labeled "imitation." They contained less fruit then jam and usually contained artificial color and flavor and, at times, a preservative. A similar trick in this country was to label condensed skim milk as "blended." This was seized.[19]

Spices a Commonly Adulterated Product

Spice continued to hold the spotlight as one of the most commonly adulterated products on sale. Bigelow[20] said in 1906: "Practically all varieties of ground spices are adulterated by some grinders and in some markets." He lists the substances commonly used then to debase spices: ground wheat and corn, ground coconut shell, almond husks, olive pits, sawdust. These may at times be colored, either by roasting, or by use of coal-tar dyes. Parts of the spice plant having no flavor value, such as pepper-shell, clove stems, or mustard bran have been imported into the country for use by the spice trade, as have been

[17] Footnote 5.
[18] Tibbles, *Foods—Their Origin, Composition and Manufacture*, p. 673 (1912).
[19] *Report of the Chemist, United States Department of Agriculture, 1911*, p. 20.
[20] Footnote 5.

other plant materials closely resembling the spice in question, but of little condimental value. Seeds of radish, rape and charlock have been used to dilute whole or ground mustard; clove and nutmeg, as well as nutmeg stems, have been found in allspice, a more expensive spice; and turmeric root has been found in ginger. As just one example, the Massachusetts State Board of Health reported the presence of ginger, mustard, mustard bran, pepper-shells, buckwheat middlings, olive pits, coconut shell, corn meal, and sawdust in ground pepper. These are typical of the reports from other states from 1900 to 1906. At times the substitution was complete. The Chief Chemist of Minnesota in 1910 found a sample of ground mace, and another sample of mustard that was made entirely of wheat flour and turmeric, artificially flavored. In the United States Department of Agriculture Yearbook for 1910, the Chief of the New York Food and Drug Laboratory complained of importations of whole spices which looked genuine but had had the essential oils removed before shipment to the United States.

State Analyses of Debased Spices

The extent of debasement of spices reported by state analysts varied widely. It is possible that this may be due in part to difference in training and skill of the analysts, particularly since most of the work requires examination by the microscope. The amount of adulteration found in pepper as reported by the various states shows wide variation. Massachusetts, in 1900, reported only 5 per cent of the samples examined were adulterated. Minnesota the next year reported 43 per cent and Michigan in 1904 reported 57 per cent. In each state, a hundred or more samples were examined, so that this range cannot be due to insufficient sampling. Mustard was seldom found unadulterated. The State of Massachusetts made a three-year study of this spice (1901-1903, inclusive) during which time over 800 samples were examined. Half of them were adulterated. This study included other spices. Allspice, cinnamon and ginger were comparatively pure, 6 per cent or less being adulterated, while 13 per cent of cloves and 45 per cent of mace samples were debased.

Spice Adulteration in Canada

Other countries reported that conditions were similar. Canada in 1903-1904 found only 47 genuine spices in 188 samples examined by Dominion analysts. Some of these came from England or from the

United States. An official Canadian report [21] is of interest as showing the decrease in adulteration of a spice following enforcement of that country's Adulteration Act (1875). This report deals specifically with white pepper—in the past one of the most heavily adulterated spices. In 1876-1877, 83 per cent of the samples examined were adulterated. The amount of adulteration slowly decreased, with some fluctuation, until in 1890 52 per cent were adulterated. By 1899, it dropped to 20 per cent, jumped up to 55 per cent in 1904, and again dropped until, in 1915, only 4 per cent of the 387 samples examined were not genuine.

Flavoring extracts were frequently adulterated. This could take two forms: (1) insufficient flavoring ingredient or (2) substitution. Both occurred. The 1906 annual report of Canadian enforcement officials [22] stated that lemon extract in Canada should contain 5 per cent oil of lemon. Their laboratory examined 110 samples of lemon extract in 1906. Fifty-seven of these contained below *1* per cent lemon oil. States in this country had then adopted a 5 per cent minimum oil content for lemon extract. Reports from Massachusetts, New Hampshire and Michigan state laboratories show 80 per cent, 65 per cent, and 40 per cent respectively were deficient in lemon oil. A frequent adulterant in both countries was oil of lemon-grass. English and French analysts also reported the same adulterant. Vanilla extract, judging by state chemists' reports, was more often than not a solution of vanillin and/or coumarin, colored with caramel.

Dr. P. B. Dunbar, retired Commissioner of Food and Drugs, stated that his first assignment on reporting to the Bureau of Chemistry in July, 1907, was to assay samples of vanilla extract. The Bureau examined this relatively unimportant food because methods had already been developed for its analysis, but dependable methods had not been perfected for detection of adulterants in the more important foods.[23]

Bread—A Less Frequently Debased Article

Bread, while a staple article of food, has been fairly free from adulteration. Even as far back as 1900, wheat flour, the main ingredient of bread, was one of the purest foods on the market.[24] The federal act of June 13, 1898, taxing mixed flour was an effective deterrent to any desire to blend other flours with wheat flour. The use of alum in

[21] *Bulletin 314, Laboratory of the Inland Revenue Department, Canada* (1915).
[22] *Bulletin 114, Laboratory of Canadian Inland Revenue Department* (1906).
[23] 1 FOOD DRUG COSMETIC LAW QUARTERLY 339 (1946).
[24] Footnote 5.

bread was only occasionally encountered. Illicit profits in the baking industry more often took the form of short weight rather than adulteration.

Adulterators of foods sometimes travel devious paths. The manufacture of artificial coffee beans previously mentioned is an excellent example, as was the proverbial "wooden nutmeg" of the Yankee trader. Then there was the ingenuity displayed by a French entrepreneur in imitating two of France's gastronomical delicacies.[25] He made artificial snails by recoating empty snail shells with fat and slime, and filling the shells with pieces of horse or cattle lung. They were sold as "Burgundy Snails". Truffles were also imitated. Chopped truffles were counterfeited by pieces of black rubber, or leather, cut to shape, and the whole "truffles" were cut from partly charred potatoes, then flavored with ether. A more modern counterfeit is occasionally used here by packers and canners of diced fruit. They take Zucca melon, dye it and flavor it, and sell it for diced citron, lemon, or cherry—either canned or glacéd. Some ingenious man in Germany injected ordinary oranges with a reddish dye solution and sold them as "blood oranges." An English physician once complained of "fraudulent foam" on beer.[26] He said a good "head" on beer is a measure of its palatability, and objected to the addition of an artificial foam producer—saponin, in this instance—since its presence destroys a useful and valuable means of judging the quality of beer. Persuasive labeling sometimes conceals an adroit fraud, as happened in the case of the man who canned pineapple cores under a label "Choice Canned Pineapple Hearts."

Testing of Suspected Products

Those were the days of gross adulterations, many of which could be detected by the "simple tests . . . that can be employed by the careful housewife with the reagents in her medicine closet and the apparatus in her kitchen" which Doctor Bigelow outlined in 1906.[27] The chemist was not completely ignored by Doctor Bigelow, himself a chemist. On the same page of the government bulletin quoted he continues:

> The manufacturer who has developed his natural senses most highly appreciates best the assistance or collaboration of the chemist, who can often come to his relief when his own powers do not avail.

[25] 89 *Scientific American* 155 (1903).
[26] 1 *Lancet* 312 (1906).
[27] Footnote 5.

The chemical methods available when the 1906 Act went into effect were simple,[28] but so were the forms of sophistication. By 1911 both were showing signs of developing along more subtle lines. The 1911 report of the chemist [29] mentions "elaborating methods that will enable the detection of the most carefully prepared imitations." Although new forms of adulteration closely followed by new methods of detection formed a pattern, early in food-law enforcement, that will probably always prevail to some extent, by the end of the first decade after the passage of the 1906 Act regulatory emphasis had swung over to another type of adulteration—spoilage, and contamination with filth —which in 1951 took 73 per cent of the field time of the Food and Drug Administration.[30] **[The End]**

• CEILING PRICES ADJUSTED TO MINIMUM PRICES •

General Overriding Regulation 32 establishes a method, pursuant to Section 402 (1) of the Defense Production Act of 1950, as amended, for the adjustment of ceiling prices to the minimum sales price fixed by certain state minimum-price laws. These state laws establish or authorize the establishment of minimum prices for sales or deliveries within the state of certain meterials. In some cases, the minimum prices established by the state laws are higher than the ceiling prices established by the Director of Price Stabilization. The 1952 amendments to the Defense Production Act provided that ceiling prices for materials sold or delivered in any state shall not be below the minimum prices of such materials fixed by that state's minimum-price law. General so-called fair trade laws were excepted from the applicable amendment.

The general overriding regulation permits the filing of applications for adjustments by individual sellers of materials subject to a minimum price law or regulation.—17 *Federal Register* 6583, as reported in CCH TRADE REGULATION REPORTS, No. 246, August 1, 1952.

[28] Footnote 23.
[29] Report cited, footnote 19, p. 55.
[30] *Annual Report, Federal Security Agency, Food and Drug Administration, 1951*, p. 3.

CRIMINAL INTENT

Under the Federal Food, Drug, and C

The Author Was a 1951-1952 Fellow in The Food Law Institute's Graduate Food and Drug Law Program at the New York University School of Law. This Discussion of *Mens Rea* Was Presented as a Research Paper Under That Program

THE LAW is today clear and unequivocal. Neither the allegation nor the proof of *mens rea* is essential in a criminal prosecution under the Federal Food, Drug, and Cosmetic Act. This has been settled law since 1943 when, in the case of *U. S. v. Dotterweich*,[1] Mr. Justice Frankfurter said:

> The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in a responsible relation to a public danger.[2]

The fact that the law is well settled should not, however, deter us from an examination of the wisdom of its policy. Criminal liability without fault, indeed, may be the cause of hardship; it should not, therefore, be accepted with complacency.

That there has been dissatisfaction with the present trend toward strict liability is apparent. The Supreme Court was itself divided in the *Dotterweich* case. Mr. Justice Murphy, speaking for a dissent of four, noted:

> It is a fundamental principle of Anglo-Saxon jurisprudence that guilt is personal and that it ought not lightly to be imputed to a citizen who, like the respondent, has no evil intention or consciousness of wrongdoing.[3]

Nor has industry unanimously accepted the subjection of their personal interest to "the interest of the larger good." In 1949, a group of millers from the Southwest presented to a subcommittee of the

[1] *U. S. v. Dotterweich*, 320 U. S. 277 (1943).

[2] Footnote 1, at pp. 280-281. Also see *U. S. v. Greenbaum*, 138 F. (2d) 437 (CCA-35 1943).

[3] *U. S. v. Dotterweich*, footnote 1, at p. 286.

and Cosmetic Act

By BURTON R. RISSMAN

Senate Committee on Interstate and Foreign Commerce a resolution which requested in effect that *mens rea* be made a requirement in criminal prosecutions under the Act. This resolution received sufficient support to be incorporated into a bill by Senator Moore, but this bill never found its counterpart in the House.[4]

Moreover, commentators on developments in the criminal law have noticed that the movement toward strict liability is antithetical to other trends in the criminal law—that is, the trend away from the emphasis on deterrence as a function of the criminal law toward the emphasis on reformation. One recent comment was:

> It is difficult to appraise the import of this development. That it is having a significant impact on the social and legal context of our time there can be no doubt. As to objectives, it is reasonably clear that the stress of the movement is less on punishment for wrongdoing, and more on social control and protection. It is a movement typical of others in our day, in which the public interests are in the ascendency over those of the individual. For the individual it has grim forebodings. He is reconciled to, if, indeed, he does not approve, the application of the doctrine to police and other minor regulations, but when employed in more serious measures, it strikes him as arbitrary and unjust. In its wider social implications the movement is tinged with capriciousness and appears not to have adequate brakes to stop it or to slow it down, unless, perhaps, they are to be applied through the due process clause of the Constitution. The development calls for an early and thorough evaluation by our legislative bodies and the courts as to its impact upon human integrity and welfare.[5]

[4] The following addition to Section 306 was called for by the resolution: ". . . (b) Neither shall the Administrator invoke criminal proceedings for violation of this Act, nor shall the courts impose criminal penalties for such violations without evidence of either (1) willful intent to violate the law, or (2) gross negligence." See Hearings before the Subcommittee of the Senate Committee on Interstate and Foreign Commerce, 80th Cong., 2d Sess., S. 1190, at pp. 51-73.

[5] Harno, "Some Significant Developments in Criminal Law and Procedure in the Last Century," 42 *Journal of Criminal Law and Criminology* 427, 432 (1951).

Finally, the Supreme Court has recently indicated that it also is aware of the need for careful re-evaluation of strict liability, and it has held that the doctrine should be applied only in those instances in which the socioeconomic developments of the last century justify the abandonment of the deep-rooted *mens rea* safeguard.[6]

This paper is an evaluation of the policy that in the regulation of the food, drug and cosmetic industries it is necessary to abandon the *mens rea* requirement. This policy is best stated by Mr. Justice Frankfurter:

> Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before starting in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.[7]

In order to help in this evaluation, this paper will trace the early developments of strict liability, the doctrine under the Food and Drug Act of 1906, and, in addition, it will consider the various criticisms of that doctrine and the reforms proposed to meet those criticisms.

Early Developments

The notion that conviction of a criminal offense, of either major or minor import, cannot be sustained without proof of *mens rea* has been, of course, a persistent one in our legal system.[8] But in 1846, in the case of *Regina v. Woodrow*,[9] a tobacco dealer was fined for having in his possession adulterated tobacco even though he had no knowledge of, or cause to suspect, the adulteration. The rationale of Baron Parke was that the public convenience outweighed the interest of the individual, so that even though

> . . . it may produce mischief because an innocent man may suffer . . . the public inconvenience would be much greater, if in every case the officers were obliged to prove knowledge. They would be very seldom able to do so.[10]

Moreover, in this same early case, Chief Baron Pollock maintained that "persons who deal in an article are made responsible for its being of a certain quality," and that in

> . . . any matter that affected the public health, it would not be at all unreasonable to require persons dealing in them to be aware of their character and quality, and to be responsible for their goodness whether they know it or not.[11]

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[6] *Morissette v. U. S.*, 342 U. S. 246 (1952).
[7] *U. S. v. Dotterweich*, footnote 1, at pp. 284-285.
[8] See *Morissette v. U. S.*, footnote 6.
[9] 15 M. & M. 404 (Exch. 1846).
[10] Footnote 9, at p. 417.
[11] Footnote 9, at p. 415.

This view was also taken in the United States three years later in *Barnes v. State*.[12] The American decisions apparently were handed down without reliance upon or, for that matter, recognition of the English decisions.[13] This fact would seem to indicate that the change was caused by the industrial revolution—that the congestion, mass distribution, and complexities of modern life created the need for new types of regulation which could not be met under the then-existing criminal law and the emphasis of that law on individual liberties to the utter exclusion of the general public welfare. Thus, strict criminal liability was devised as the means, by dint of criminal sanctions, of regulating industries affecting the public health. This change was accompanied by a change in philosophy and emphasis; the conduct of a particular defendant received more attention than did his culpability.

Mens Rea Under the 1906 Act

It is often said that the Federal Food, Drug, and Cosmetic Act would be emasculated if the prosecution was required to prove criminal intent. Is there any empiric basis for such a statement? Experience under the Act of 1906 seems to furnish that empiric basis.

Many judges, bred in the tradition that criminal intent was always essential, continued after the Act was passed to charge juries to that effect. Almost without exception acquittals resulted when these charges were made. It is possible that in those cases there was not sufficient proof that the article was either misbranded or adulterated. However, it is unlikely that that was the case. For example, in *U. S. v. Bowers*,[14] the defendant contended that the adulteration of certain food was done by his clerks during his absence and without his knowledge. The court instructed the jury that knowledge, or reason to know, of the adulteration was a requisite part of the government's case, and the jury accordingly returned a verdict of not guilty. As a result of this decision, neither this defendant nor anyone else is provided with the incentive to hire careful employees or carefully to supervise the work of the employees he does have.[15] Moreover, no premium for care is

[12] 19 Conn. 398 (1849).

[13] The development of the doctrine is thoroughly considered in Sayre, "Public Welfare Offenses," 33 *Columbia Law Review* 55 (1933), and in *Morissette v. U. S.*, footnote 6.

[14] Notice of Judgment No. 5072 (DC Tenn., 1916).

[15] *U. S. v. Weeks*, Notice of Judgment No. 3332 (DC N. Y., 1913), produced a like result on a misbranding charge. Defendant contended that the article was misbranded due to the mistake of an employee who had no orders to misbrand. The court charged that the defendant was guilty only if he "knowingly stands by and permits that to be done which he knows to be criminal, and does not forbid it."

given by the case *U. S. v. Tetz*,[16] where the trial judge charged the jury that if it, the jury, found that the milk defendant sold was watered either by accident or by a third party, a verdict of not guilty must be returned. The jury so found, and the defendant was acquitted.[17] If the objective of a food and drug law is consumer protection, such decisions are hardly designed to do the job. Rather, they tend to indicate that a law under which the government would be required to prove *mens rea* would be ineffective.

A further backlog of experience is provided by the Sherley Amendment of 1912. That amendment provided, in effect, that a drug was misbranded if its labeling contained therapeutic claims which were false and fraudulent. The word "fraudulent," when taken in its accepted legal meaning, refers, of course, to *scienter*—an intent to deceive.[18] The results under the amendment were what was to be expected. Suppose, for example, that a horse liniment is sold as a cure for bronchitis, influenza, laryngitis, pneumonia, croup, pulmonary tuberculosis and locomotor ataxia; or suppose that a brew of horsetail, a weed found along the railroad tracks of western Pennsylvania, is labeled as a cure for diabetes.[19] Today there would be little doubt that such spurious cures should not be marketed. Yet, under the Sherley Amendment they were marketed with impunity for the simple reason that the manufacturers of these products were excellent salesmen; they were able to sell the juries which tried them of their good faith.

Moreover, even if one were to say that *mens rea* is not an onerous burden of proof for the government to sustain, the cases under the Sherley Amendment indicate collateral problems insofar as the proof of misbranding is concerned. The general technique of the defense in these cases was to introduce into evidence such things as testimonials from satisfied users [20] and letters sent by defendant to his own lawyers,[21] all of which were introduced for the purpose of proving that the defendant honestly believed the product had those therapeutic benefits claimed for it. Such evidence is, of course, hearsay on the issue of misbranding—that is, on the question as to whether the product actually had the claimed benefits. If the good faith of the defendant

[16] Notice of Judgment No. 6874 (DC Wash., 1919).

[17] Mistake was held insufficient to support a conviction on a misbranding charge in *U. S. v. Italian Importing Company*, Notice of Judgment No. 6938 (DC N. Y., 1919).

[18] *Seven Cases of Eckman's Alternative v. U. S.*, 239 U. S. 510 (1916).

[19] *See* Dunn, *Federal Food, Drug, and Cosmetic Act*, pp. 1158-1159 (1938).

[20] *Dr. J. H. McLean Medicine Company v. U. S.*, 253 F. 694 (CCA-8, 1918).

[21] *Chichester Chemical Company v. U. S.*, 49 F. (2d) 516 (CA D. of C., 1931).

were not also in issue, the testimonials would be inadmissible, but, as soon as *mens rea* becomes an issue in the case, such materials may be admitted into evidence. The result is, naturally, that the jury tends to confuse the two issues, and the burden of proving that the article in question was misbranded accordingly becomes greater.

Critical Evaluation of Present Act

As the introductory remarks to this paper indicated, there is much concern over the loss of protection of individual interests that results when the individual is convicted without reference to his subjective guilt. The criticism is unquestionably valid. But, on the other hand, it also is unquestionably true that, due to the impersonal market of modern life, the consumer must rely on governmental protection in the food and drug field. If such protection can effectively be obtained through some means other than strict liability, continuation of strict liability would, of course, be unjustifiable. But if no other adequate means of control does now exist, the protection necessary for social interests demands that strict liability, provided it does the job claimed for it, be continued to be used as a means of regulation. Thus, there are two questions which must be answered. First, does strict liability serve the necessary regulatory function? Second, even if strict liability does so serve, is there an adequate alternative?

It is desirable in the regulation of the food and drug industries not only to police these industries but also to promote increased care and efficiency.

> It seems probable that most persons and businesses within their potential orbit of strict liability can improve their method of operation. Strict liability is the gadfly which stimulates the greater effort; this redounds to the public good.[22]

Critics say that this is an assumption never proved to be true—that in many businesses there is not necessarily room for improvement, inasmuch as the businessman is faced by the practical limitations imposed by the cost of operation.[23] But here, again, experience has shown that manufacturing controls which were once thought to be the best devisable, were improved when the manufacturer was prosecuted or threatened with prosecution for a violation which, at the time, seemed unavoidable. If there is no incentive to wrestle with a problem, that problem may, indeed, seem to be insurmountable. The incentive

[22] Hall, *General Principles of Criminal Law*, p. 300 (1947).

[23] Hall, work cited, at pp. 300-301.

provided by the threat of prosecution has resulted in the solution of many of these so-called insurmountable problems. This not only redounds to the public good; it also gives to the manufacturer or industry which solves the problem a competitive advantage.

It is also suggested that even though criminal prosecutions do serve as the desired prod to improvement, there is no evidence that such prosecutions would not be as effective if *mens rea* were required. The argument runs that *mens rea* is also difficult to prove in many of the major crimes—such as receiving stolen goods—and that no one would suggest to impose strict liability for these offenses.[24] However, a careful examination of this argument reveals its sophistic tendency. First of all, the experience under the Act of 1906 indicates that the proof of *mens rea* was often a difficult burden for the government, and that adulterated or misbranded products continued to be marketed because juries believed in the good faith of the manufacturers of those products. Moreover, experience has also shown that evidence introduced for the purpose of proving good faith tended to confuse juries on the basic issue of misbranding. In addition, the fact that a crime such as the receiving of stolen goods does require proof of *mens rea* does not alter the case for strict liability in the food and drug field. It is necessary to have manufacturers of foods and drugs; it is highly desirable that they be careful and efficient. It is undesirable, on the other hand, to have receivers of stolen goods. The public interest does not require that they be prodded to care and efficiency, but rather that they be prodded into other, more law-abiding endeavors. Our interest lies in the reformation of these major criminals; thus, culpability is much more important from the point of view of society, as well as the individual, in the so-called major crimes than it is in the case of a misbranding or adulteration.

Another criticism of strict liability as a prod to increased efficiency is that the Act demands perfection and, that, in this imperfect world of ours, it is a manifest injustice to prosecute a man for falling short of perfection. This criticism has reference to Section 402 (a) (3) of the Act, which provides that "a food shall be deemed to be adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food." Inasmuch as it is impossible to process certain foods, such as wheat, so that they remain aseptically pure, this section demands an unattainable perfection.[25]

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[24] Hall, work cited, at p. 306.

[25] See Hearings, footnote 4.

Apparently the processor is left, without safeguards, to the caprice of the Administrator. But it is in just such a case that the courts have indicated that they will provide safeguards. The *de minimis* rule is one such judicial check.[26] Another is inferentially suggested in the case of *U. S. Gerber Products Company*.[27] The defendant in that case urged that it was impossible in commercial practice entirely to eliminate all contamination. The jury was instructed:

> . . . that it was not the intention of Congress to include as a criminal offense the presence of filthy, putrid or decomposed matter in such infinitesimal and inconsequential quantities as even the highest degree of care could not eliminate.[28]

This instruction recognizes the limitations imposed upon commercial enterprise, yet it does not remove the incentive to improve manufacturing practices.

There are, moreover, administrative safeguards. Section 305 provides that a violator be given notice and hearing before the criminal violation is reported to a United States attorney. This hearing is not a jurisdictional requisite to the institution of criminal proceedings but it is, nevertheless, granted in the vast majority of cases. At this hearing the person heard may show that the violation was unavoidable; that manufacturing procedures were careful, efficient and modern; that he was acting in accordance with administration recommendations or educational programs; that continued research directed toward the improvement of procedure and controls is conducted; or anything else of a like nature. The Administrator may be satisfied that no advantage is to be gained from prosecution, and, consequently, he will not report the case. The public interest is thus adequately served by the notice and warning.[29]

There exists, in addition, the administrative safeguard—applicable to all of the criminal law—of the discretion of the prosecutor. As to this, Mr. Justice Frankfurter said:

> In such matters the good sense of prosecutors, the wise guidance of trial judges, and the ultimate judgment of juries must be trusted. Our system of criminal justice necessarily depends on "conscience and circumspection in prosecuting officers," . . . [citation omitted] even when the consequences are far more drastic than they are under the provision of law before us.[30]

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[26] *See*, for example, *U. S. v. Gerber Products Company*, footnote 27, below. If the *de minimis* rule were not applied, it would, nevertheless, seem better to change Section 402 (a) (3) than to change from strict liability.

[27] Notice of Judgment No. 7808 (1946).

[28] A verdict of not guilty was returned.

[29] See Section 306 of the Act.

[30] *U. S. v. Dotterweich*, footnote 1, at p. 284.

This may appear as a rather illusory check and balance, but it must be remembered that prosecutors are limited by the exigency of time. Not all violations can be prosecuted. Thus, discretion and selection must be used and, parenthetically, this is true whether or not *mens rea* is required. Enforcement of the law would be impeded, due to the lack of public support, if the wrong people—that is, people who were acting intelligently, carefully, efficiently, conscientiously and within the spirit as well as the letter of the law—were often prosecuted, while malevolent, slovenly, inefficient or inept violators were let off with a warning. Therefore, the administration best serves its own purpose by selecting for prosecution those who most deserve it.[31] Doubtless, not everyone will agree on the exercise of this administrative discretion, but whatever opportunity there is for arbitrariness is balanced by the practical needs of law enforcement.

It appears then that strict liability is a suitable means of accomplishing the objectives of a food and drug law. But we must also inquire into the suitability of the suggested alternatives. The most basic alternative is to require proof of guilty intent in the case of prosecutions, but not for other sanctions. The contention is that seizures and injunctions are adequate to provide consumer protection in those instances in which *mens rea* is impossible of proof.

But analysis of these sanctions does not bear out this contention. Seizures offer only limited protection. Quite obviously, not every article shipped in violation of the law can be seized before it reaches the consumer. If only part of the total production is seized, the profits from the part not seized might justify the continuation of the same bad manufacturing practices and inefficiencies, whether they are intended or not. Moreover, inasmuch as no moral stigma attaches to seizures, the prod to improvement of methods is not as great as it would be if prosecution were threatened.

It is likewise apparent that injunctions offer inadequate consumer protection. Courts are reluctant to grant injunctions; it is an onerous sanction to have hanging over any business. Thus, proof of the likelihood of repeated violations is required, and a defendant might defeat an injunction merely by firing lax employees or telling the court that

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[31] This does not mean that only willful violators are those who deserve to be prosecuted. That would be reading an administrative *mens rea* requirement into the Act. Others must also be prosecuted if the Act is to serve as an incentive to improvement.

he was going to retool.[32] In addition, it is not clear that, even if the injunction were granted, the businessman would be in a better position than he is under the present law, for if he were to violate the injunction—no matter how innocently—he would be subject to citation for criminal contempt, and not as many safeguards are available in a contempt proceeding as in a criminal trial.

Another suggested alternative is that when the case involves possible imprisonment, as does the present Act, intent should be required, but the burden of proof shifted to the defendant.[33] The present Act does reflect this philosophy in certain situations where primary responsibility can be shifted elsewhere.[34] The experience under these sections is so limited that it is impossible to determine their effectiveness. Nevertheless, it is safe to hazard the guess that if this philosophy were extended to the entire Act, the Act would be rendered less effective. It might be easy to convince a jury of good faith, as was done in cases under the Sherley Amendment, but the injurious or fraudulent product remains on the market. Again, if good faith is the all-important feature, there is no incentive to improvement or conscientiousness; there is no protection from carelessness, indifference or ignorance.

Another suggested reform is so well put and, apparently, so well thought out that it deserves to be stated in full. It is as follows:

> The problem of protecting the public welfare, so far as its bulk is concerned, would be transferred mostly to licensing and administrative agencies, leaving the drastically reduced volume of willful violations to be disposed of by specialized courts. Thus, for unscrupulous individuals, the criminal law, amplified to allow adequate dealing with crimes that are very serious in modern conditions, would be used much more frequently than in the past. On the other hand, the irrational trial of reputable persons in a criminal court would be discontinued. Instead, sound legislation, inspection, licensing, information, investigation by boards, informal conferences, and publicity are much more likely means of influencing legitimate business.
>
> For the incompetents who try, but simply cannot conform to decent standards, there is no alternative save to bar them from continuing the conduct which is harmful to the public—whether that is driving an automobile, or supplying milk, or operating a public bar. It is undoubtedly true that the penal law functions much less onerously than would revocation of a license to do business. But this does not support the continuance of an anomalous strict "penal" liability. The community is entitled to protection from inefficient persons who engage in potentially dangerous vocations or activities. . . . The only recourse in some cases must be the termination of the business or other activity.[35]

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[32] *See*, for example, *U. S. v. Cowley Pharmaceuticals*, Notice of Judgment No. 7369 (DC Mass., 1948).

[33] Sayre, work cited, at p. 79.

[34] The reference is to Section 303 (c) (1) and to Section 303 (c) (4).

[35] Hall, work cited, at pp. 309-310.

This recommendation is premised on the adequacy of licensing. In addition to being more onerous than the present method of regulation, licensing is, however, inadequate for two reasons. First, it is not an adequate means to protect the public interest. Second, it would impede the Administration.

That license revocation is an onerous sanction is obvious. The author of the recommendation admits this, but he justifies it on the ground that it would result in increased consumer protection. Would this increased consumer protection in fact exist? We now control automobile drivers and saloonkeepers by licensing them. It is true that if they are inefficient or incompetent, we can, and do, revoke their licenses. But they must first be given the opportunity to exhibit this inefficiency or incompetency. The public suffers while we learn who is, and who is not, efficient. The licensing of automobile drivers does not prevent accidents due to obvious incompetency. The licensing of saloons does not prevent sales of liquor to minors and drunks. It could be catastrophic in the food and drug field, where the potential for harm is great, to wait while we screen the bad from the good. We must ask if one misbranding or adulteration would be sufficient grounds for revocation, or must the public suffer two, three, or even ten, violations before we decide that a man is not fit to remain in the business. The revocation would be a locking of the barn door after the escape of the horse.

Moreover, to a food or drug manufacturer, revocation of a license to remain in busines would mean what disbarment means to the lawyer. Although it is not a criminal sanction in the traditional sense, it is certainly penal in nature. The revocation, which presumably could be made without proof of culpability, would thus entail strict liability. To distinguish this from the present law is to engage in conceptualism.

Finally, licensing would interfere with the administration of the law. It requires time, money and personnel efficiently to operate any worth-while licensing system. Today that time, money and personnel is engaged in inspecting, sampling, testing, advising and planning. To the extent that these resources would be engaged in the purely clerical function of licensing, proper law enforcement and supervision would be adversely affected.

Conclusion

It has been shown that strict liability is a very valuable tool in the enforcement of the Act, and that no satisfactory alternative has as yet

been advocated. There can be but one conclusion—namely, that we must continue to use strict liability in our food and drug laws. It is necessary, however, to issue a caveat. The fact that strict liability is now useful and necessary does not mean that it will continue to be useful forever.[36] Conditions change. Developments in our technology, economic structure, or legal system—or in all three—may require us to use completely different enforcement procedures. We must, therefore, continually evaluate this doctrine in the light of the new conditions which may exist. Only then will we be justified in continuing to use it. **[The End]**

• RECENT FTC MISREPRESENTATION ORDERS •

Beverage flavoring . . . The commission has approved a stipulation in which the manufacturer of a beverage flavoring has agreed to cease representing that its preparation is made solely from lemons or lemon juice, or that the flavor is derived solely from lemons or that the flavor is the true flavor of fresh lemons. (Released July 13, 1952.)

Medicinal preparations . . . Under the terms of a consent settlement, the manufacturer of an ear-vibrator device sold in combination with a home treatment for deafness agreed to refrain from representing that the use of said preparations—either singly or together—would have any beneficial effect upon deafness or impaired hearing, other than affording temporary relief from such condition. (Released July 10, 1952.)

The manufacturer of a diathermy device is charged with falsely representing that the device can be safely used by the lay public to relieve the pains of chronic arthritis, neuritis and rheumatism. (Complaint issued June 16, 1952; released July 5, 1952.)

The manufacturer of a vitamin and mineral compound is charged with falsely representing that the preparation is a competent and effective treatment for skin disorders, nervousness, restlessness, stomach distress and neuritis. (Complaint issued June 29, 1952; released July 10, 1952.)

Sellers of a medicinal preparation are charged with falsely representing that their product is an effective treatment for all diseases or conditions caused by vitamin or mineral deficiencies; that it gives fast relief in muscular pain; and that it constitutes an effective treatment for a weak, rundown condition. (Complaint issued June 30, 1952; released July 18, 1952.)—CCH TRADE REGULATION REPORTS ¶ 11,131; ¶ 11,125; ¶ 11,126; ¶ 11,130; ¶ 11,138.

[36] Nor does it mean that it should be extended to other fields without a re-examination of the need for it in those fields.

Michigan Food Law

By EDWIN L. HARDING

This Article Is Reprinted, with the Permission of the *Michigan State Bar Journal*, from Its April, 1952 Issue.
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THE PURE FOOD LAWS of Michigan are contained in Chapter 91 of Michigan Statutes Annotated. In addition to the basic pure food laws, this chapter contains special provisions regarding numerous food items, and there are many special acts regarding particular foods. Consequently, only a brief comment on a few aspects of the subject can be given within the limits of this article.

The basic food law of Michigan is Public Act 193 of 1895, "an act to prohibit and prevent adulteration, fraud and deception in the manufacture and sale of articles of food and drink" (Section 12.871, and following, MSA). Section 1 prohibits adulteration and misbranding, and Sections 2, 3 and 3 (a) define food, adulteration, and misbranding, respectively. [For text of sections, see page 511.] The definitions of adulteration and misbranding are similar to those of the Federal Pure Food Law of 1906, but are not as broad as those of the Federal Food, Drug and Cosmetic Act of 1938. Section 19 provides that violation of any of the provisions of the law constitutes a misdemeanor, punishable where not otherwise specifically provided, by a fine of not less than $25 nor more than $500, or by imprisonment in the county jail for a period of not more than 90 days, or by both such fine and imprisonment in the discretion of the court.

Michigan manufacturers of foods, engaged in interstate commerce, and their attorneys have tended to devote most of their attention to the provisions of the Federal Food, Drug and Cosmetic Act of 1938. (21 USCA Section 301, and following.) A vast amount of literature exists regarding the provisions of the federal law,[1] whereas very little

[1] CCH FOOD, DRUG AND COSMETIC LAW REPORTS (two vols.; Vol. 1 covers federal laws, and Vol. 2 covers state laws and product liability). The Food Law Institute, Inc., is publishing a series of books

(Continued on page 512)

PERTINENT SECTIONS OF MICHIGAN FOOD LAW

"Sec. 12.872 FOOD DEFINED. Sec. 2. The term food as used herein shall include all articles used for food, drink, confectionery or condiment intended to be eaten or drunk by man or other animals, whether simple, mixed or compound. [Compiled Laws, 1948, Sec. 289.82.]

"Sec. 12.873 ADULTERATED DEFINED. Sec. 3. An article shall be deemed to be adulterated within the meaning of this act:

"First, If any substance or substances have been mixed with it so as to lower or depreciate or injuriously affect its quality, strength or purity;

"Second, If any inferior or cheaper substance or substances have been substituted wholly or in part for it;

"Third, If any valuable or necessary constituent or ingredient has been wholly or in part abstracted from it;

"Fourth, If it consists wholly or in part of a diseased, decomposed, putrid, infected, tainted or rotten animal or vegetable substance or article, whether manufactured or not, or in the case of milk, if it is the product of a diseased animal;

"Fifth, If it is colored, coated, polished, bleached or powdered whereby damage or inferiority is concealed, or if by any means it is made to appear better or of greater value than it really is;

"Sixth, If it contains any added substance or ingredient which is poisonous or injurious to health: Provided, That nothing in this act shall prevent the coloring of pure butter. [Compiled Laws, 1948, Sec. 289.83.]

"Sec. 12.874. MISBRANDED DEFINED: VARIATIONS AND EXEMPTIONS: SALE OF FOOD, MANNER. Sec. 3 (a). An article shall be deemed to be misbranded within the meaning of this act:

"First, If it is an imitation of or is offered for sale under the name of another article;

"Second, If it is labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package;

"Third, If in package form every package, box, bottle, basket or other container does not bear the true net worth, excluding the wrapper or container, which shall be stated in terms of pounds, ounces and grains avoirdupois weight or the true net measure, which measure, in case of liquids, shall be in terms of gallons of two hundred and thirty-one (231) cubic inches or fractions thereof, as quarts, pints and ounces or the true numerical count, as the case may be, expressed on the face of the principal label in plain English words or numerals, so that it can be plainly read: Provided, however, That reasonable variations shall be permitted and tolerances therefor and also exemptions as to small packages shall be established and promulgated by the dairy and food commissioner: Provided, however, That no penalty of fine, imprisonment or confiscation shall be enforced for any violation of subdivision third (3rd) of this section prior to September 1, 1914, as to goods in the hands of wholesalers or retailers when this act takes effect or received prior to January 1, 1914. The provisions of this subdivision shall not apply to beverages in glass containers;

"Fourth, If the package containing it or its label shall bear any statement, design or device regarding the ingredients or the substances contained therein, which statement, design or device shall be false or misleading in any particular: Provided, That the provisions of this act shall not apply to mixtures or compounds recognized as ordinary articles or ingredients of articles of food, if each and every package sold or offered for sale bear the name and address of the manufacturer or jobber or retail merchant with an established business, and be distinctly labeled under its own distinctive name, and in a manner so as to plainly and correctly show that it is a mixture or compound and is not in violation of any of the foregoing provisions of this act. Every article of food as defined in the statutes of this State shall be sold by weight, measure or numerical count and as now generally recognized by trade custom, except where the parties otherwise agree, and shall be labeled in accordance with the provisions of the food and beverage laws of this state. Only those products shall be sold by numerical count which cannot well be sold by weight or measure. All foods not liquid, if sold by measure, shall be sold by standard dry measure, the quart of which contains sixty-seven twenty one-hundredths (67-20/100) cubic inches, providing that the provisions of this section shall not apply to fresh fruit and vegetables. [Compiled Laws, 1948, Sec. 289.83a.]

* * *

A uniform state food, drug and cosmetic act has been drafted in harmony with the federal law, and it, or laws patterned on the federal Act of 1938, has been passed by about 25 states. Some efforts have been made to secure the adoption by the State of Michigan of the uniform state law, but so far little interest has been generated in the matter.

literature exists concerning the Michigan state law outside of the statute books and cases. Nevertheless, the Michigan law vitally affects the lives and health of its citizens, because, after all, most transactions are intrastate. As Dr. M. A. Nelson, chief of the Bureau of Marketing and Enforcement of the Michigan Department of Agriculture, recently stated:

> So few people realize that the Federal Food and Drug Administration cannot act in any food law violation unless or until interstate shipment can be proven. Therefore, state food laws and regulations, and the enforcement of the same, are imperative to protect our own people against adulteration, misbranding and insanitary conditions.

Police Power

Laws regulating the sale of articles of food and drink are enacted pursuant to the police power of the state, which extends to the protection of the health, as well as to the lives and property, of the citizens.[2]

But the Michigan Supreme Court made it clear in *Carolene Products Company v. Thomson,* 276 Mich. 172, 267 N. W. 608 (1936), that the police power of regulation does not include the absolute prohibition of trade in useful and harmless articles of commerce. In this case, a statute was held invalid which prohibited the sale of milk to which any fat or oil other than milk fat had been added as applied to a harmless and nutritive milk product containing nut oils and skimmed milk. The court stated at page 610 in part as follows:

(Footnote 1 continued)
on food laws, the first volume having already been published under the title *Federal Food, Drug and Cosmetic Law, Administrative Reports, 1907-1949* (Commerce Clearing House, Inc.) (1951); Kleinfeld and Dunn, *Federal Food, Drug and Cosmetic Act—1938-1949;* Dunn, *Federal Food, Drug and Cosmetic Act* (1938) and Index (1940); Herrick, *Food Regulation and Compliance* (two vols., 1947); Toulmin, *The Law of Foods, Drugs and Cosmetics,* (1942); FOOD DRUG COSMETIC LAW JOURNAL, quarterly from March, 1946, through December, 1949, monthly from March, 1950, publishes, among other things, the proceedings of the annual meetings of the Section of Food, Drug and Cosmetic Law of the New York State Bar Association and the proceedings of the annual meetings of the Division on Food, Drug and Cosmetic Law in the Section of Corporation, Banking and Business Law of the American Bar Association. The *Quarterly Bulletin of the Association of the Food and Drug Officials of the United States* contains much material regarding state food laws.

[2] *People v. Snowburger,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 46,005, 113 Mich. 86, 71 N. W. 497 (1897) (adulterated mustard); *People v. Worden Grocer Company,* 118 Mich. 604, 77 N. W. 315 (1898) (substandard vinegar); *People v. Rotter,* 131 Mich. 250, 91 N. W. 167 (1902) oleomargarine); *People v. Hinshaw,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 46,005, 135 Mich. 378, 97 N. W. 758 (1904) (adulterated vanilla extract); *People v. Dehn,* 190 Mich. 122, 155 N. W. 744 (1913) (adulterated sausage); *Johnson v. Michigan Milk Marketing Board,* 295 Mich. 644, 295 N. W. 346 (1940) (upholding assessment provisions of Michigan Milk Marketing Act); *Johnson v. Figy,* 314 Mich. 548, 22 N. W. (2d) 893 (1946) (milk); *Thayer v. Michigan Department of Agriculture,* 323 Mich. 403, 35 N. W. (2d) 360 (1949) (chocolate drink); *People v. Breen,* 326 Mich. 720, 40 N. W. (2d) 778 (1950) (yellow oleomargarine).

> The Constitution guarantees to citizens the general right to engage in any business which does not harm the public. . . . The constitutional right to engage in business is subject to the sovereign police power of the state to preserve public health, safety, morals, or general welfare and prevent fraud. In the exercise of the police power, there must be not only a public welfare to be conserved or public wrong to be corrected, but there must be also a reasonable relation between the remedy adopted and the public purpose. . . .
>
> Possibility of wrong to the public does not always justify prohibition of a business. Regulation only may be the reasonable remedy.

The *Carolene* case was one of the first cases to recognize the foregoing principles. As stated by the court in *Thayer v. Michigan Department of Agriculture*, 323 Mich. 403, 35 N. W. (2d) 360 (1949):

> The early cases placed practically no restrictions on the power of the legislature in this field of regulation. However, in recent cases the courts have held that the regulations must be reasonable and are limited by the due process clause of the State and National Constitutions.

Statutes reasonably regulating the sale of articles of food and drink have been universally upheld.[3]

Intent

Under these statutes, the risk is upon the seller, at his peril, of knowing that the article he offers for sale is not adulterated, and ignorance of the fact or state of things contemplated by the statute will not excuse its violation, despite the general rule (which is by no means universal) that there can be no crime without a criminal intent.[4] The absence of intent may, however, affect the size of the penalty imposed.

Michigan Department of Agriculture

The general administration and the powers and duties of the Michigan Department of Agriculture are vested in a bipartisan commission of agriculture composed of five members appointed by the

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[3] *People v. Worden Grocer Company*, cited at footnote 2, statute prescribed standards for vinegar; *People v. Rotter*, cited at footnote 2, statute prohibited sale of yellow oleomargarine but not white oleomargarine; *People v. Dehn*, cited at footnote 2, statute prescribed standards for sausage; *Thayer v. Michigan Department of Agriculture*, cited at footnote 2, statute prescribed standards for chocolate milk products.

[4] *People v. Snowburger*, cited at footnote 2; *People v. Hinshaw*, cited at footnote 2; *People v. Worden Grocer Company*, cited at footnote 2. An unsuccessful attempt was made in 1949 by a group of southwest millers of corn and wheat to secure passage of an amendment to the federal law to provide that a criminal conviction for violation of the federal law require proof of willful intent or gross negligence. This emasculating effect of such a provision is discussed by Mr. James M. Best, general counsel, Quaker Oats Company, in an article in FOOD DRUG COSMETIC LAW QUARTERLY, March 1949, Vol. 4, No. 1, p. 68, entitled "The Significance of the Proposed 'Moore' Amendment."

governor for six-year staggered terms.[5] The commission is authorized to appoint and employ a director of agriculture, who shall continue in office at the pleasure of the commission. The intent of the law is to provide a non-political direction of the department's activities, so as to permit a greater continuity of policy and personnel.

The Department of Agriculture is in charge of the enforcement of the Michigan food laws, and in addition, it is in charge of seed inspection and analysis for purity and germination, feeds and fertilizers inspection, economic poisons inspections and analyses, insect, pest and plant disease control, and animal disease control. It cooperates extensively with the United States Department of Agriculture and administers jointly with that department a wide variety of agricultural activities, such as market news, crop reporting, and agricultural marketing research.

An excellent summary of the Michigan food laws and the work of the Michigan Department of Agriculture is contained in the fourteenth biennial report of that department covering the years 1949-1950, at page 79, as follows:

The Michigan Department of Agriculture is vested by law with the responsibility of administering all State laws pertaining to:

(1) the manufacture and sale of articles of food and drink;

(2) the sanitary conditions in any place where any food or drink products are manufactured, stored, deposited or sold;

(3) the standardizing, grading, packing, storing and marketing of farm products; and,

(4) the weights and measures, and the testing and calibrating of weighing and measuring devices.

The Bureau of Marketing and Enforcement has been designated as the division of the Department responsible for enforcing all of these laws, except those pertaining specifically to dairy products. Over 50 State laws and 24 regulations pertaining to food or weights and measures are enforced by this Bureau. The provisions of these laws and regulations make—

(1) every food handling establishment in the State subject to inspection to see that sanitary requirements are met;

(2) every article of food or drink being offered for sale subject to examination to see that it is not adulterated or misbranded; and

(3) every weight, measure, weighing and measuring device subject to test for accuracy.

Several laws administered by the Bureau provide for the regulating and licensing of specific types of operations in the manufacturing, processing, marketing or selling of food or drink products, i.e.: Commission Merchants, Canning

[5] The information herein regarding the Michigan Department of Agriculture is taken from the fourteenth biennial report of such department, covering the years 1949-1950.

Factories, Frozen Food Locker Plants, Soft Drink Bottling Plants, Soft Drink Syrup and Extract Registrations, Non-Alcoholic Beverage Registrations, Potato Graders, Potato Dealers, Farm Produce Storage Warehouses, Weighmasters at Livestock Yards, and Sausage Manufacturers and Dealers.

In order to administer the food laws, the department has instituted a program of constant checking of conditions in the field relative to the preparation, labeling, and merchandising of foods. During the two-year period, 1949-1950, the field staff of the Division of Foods and Standards of the Bureau of Marketing and Enforcement, completed the following activities, among other things:

(a) Inspection of 82,626 establishments of all types handling food. The division's inspectors are expected to make a thorough sanitary inspection of all food establishments in their respective districts. During this period "insanitary notices" (warnings to place establishments in a sanitary condition by a specified date) were issued against eating and/or drinking establishments, retail food stores, bakeries (wholesale and retail), slaughterhouses, food-processing plants, soft-drink bottling plants, food trucks, and frozen-food locker plants; likewise, criminal convictions were obtained on the following grounds: insanitary conditions, misbranding, adulteration, short weight or measure, not properly licensed, no apple-advertising stamps, false weighing or measuring device, false advertising, interfering with an inspector, no oleomargarine placard, insanitary bread shipment, violation of soft-drink law, illegal possession of seized merchandise and illegal transportation of dead animals.

(b) Approval of the disposition of 2,103 lots of food products that had been placed under seizure because of failure to meet the requirements of state laws. Inspectors of the bureau have authority to seize adulterated, impure, unwholesome or misbranded food or drink products being offered or kept for sale. These seized products are then either brought into compliance with the laws and regulations by reconditioning, regrading or relabeling, or diverted to channels other than food for human consumption. The short-weight or -measure items, including other than food products, are either brought up to the quantity declared or bulked. The reasons for seizure are tabulated for statistical purposes by the bureau substantially as follows: (1) Adulteration: (a) fraud or deception; (b) injurious ingredients; (c) filth or decomposition; (d) worm, insect or rodent infestation; (e) fire, smoke or water damage; (f) unwholesome. (2) Misbranding:

(a) below grade declared; (b) improper labeling; (c) no grade or size declaration; (d) no labeling of any kind. (3) Short weight or measure. (4) Soft-drink products not registered. (5) Not properly licensed.

(c) Testing of 148,001 weighing and measuring devices throughout the state, 105,848 of which were found to be accurate, subsequently approved and sealed; 42,153 were found to be inaccurate and condemned for use until brought into compliance.

(d) Reweighing of 90,890 packages and loads to check the accuracy of the weight or measure declared, 54,206 of which were approved as accurate, while 36,684 were condemned as being short of the declared weight or measure.

State, federal and local officials cooperate extensively in the enforcement of state, federal and local food laws.[6]

Products Liability Law

The basis of liability in food-products injury cases presents the same difficulty in Michigan as in other states. In one of the leading Michigan cases (*Hertzler v. Manshum*, 228 Mich. 416, 200 N. W. 155 (1924)), Mr. Justice Wiest stated at page 156 in part as follows:

> The cases cited by counsel, and other cases upon the question of the liability of the manufacturer of foodstuffs to the ultimate consumer, appear hopelessly at variance. Some deny liability at all; some recognize liability upon an implied warranty of wholesomeness, some plant liability upon an implied negligence in case of foreign poisonous substances; while others hold liability depends upon a substantive showing of negligence. We experience no inclination to enter upon a review of such cases. We have before us a case of a foreign poisonous substance in flour, and our opinion is confined to such a case.

The *Hertzler* case was a suit for damages resulting from the consumption of foods made from flour which contained arsenate of lead. The court used language which indicated that an action for breach of warranty in the sale of food could be maintained only on proof of

[6] Michigan authorities give considerable assistance to the federal Food and Drug Administration in Michigan seizure actions. Under Michigan law, as is the case of the laws of many of the states, whenever any food product is suspected of being in violation of any of the food laws, it may be immediately seized by the Michigan authorities. It takes several days for the federal officials to obtain the necessary authority for seizure, and by that time an unreliable dealer could move the products to another location or attempt to sell or conceal them, so that contact is lost with the violative goods. Consequently, it is the practice of the state officials to cooperate with the federal officials and on their request to place an immediate seizure on suspected goods for a short time in order to hold them until the federal officials obtain the necessary authority for federal seizure.

negligence, and that to sustain the action there must be shown a want of a high degree of care.

In *Kenower v. Hotels Statler Company, Inc., et al.*, 124 F. (2d) 658, (CCA-6, 1942), the federal court made an extensive review of the Michigan authorities,[7] in order to ascertain the Michigan law, as it was required to do by *Erie Railroad Company v. Tompkins*, 304 U. S. 64, 58 S. Ct. 817, and decided that the language of Mr. Justice Wiest in the *Hertzler* case was specifically made applicable only to a foreign poisonous-substance case and that the general Michigan rule is as follows (at page 662):

> From the above, it is implicit that the liability of an insurer results from breach of warranty in the case of food, which is used in the usual manner by the consumer.
>
> We are of the opinion that under the authority of *Hoover v. Peters*, 18 Mich. 51, defendant hotel company would be liable on breach of warranty without proof of negligence, if it were found that it had caused plaintiff to be served infected clams from which his illness resulted.

The court also held that while the doctrine of *res ipsa loquitur* is not recognized in Michigan, the jury can draw reasonable inferences from the evidence.

As a result of the uncertainty as to the exact basis of liability in these cases, it is customary to have two counts—one on implied warranty and one on negligence.

General authorities on the question of food products liability law are referred to below.[8]

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[7] *Hoover et al. v. Peters*, 18 Mich. 51 (1869); *Copas v. Anglo-American Provision Company*, 73 Mich. 541, 41 N. W. 690 (1889); *Cook v. Darling*, 160 Mich. 475, 125 N. W. 411 (1910); *Hertzler v. Manshum*, 228 Mich. 416, 200 N. W. 155 (1924); *Smolenski v. Libby, McNeill & Libby*, 280 Mich. 329, 273 N. W. 587, 588 (1937); *Cheli v. Cudahy Bros. Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 46,005, 267 Mich. 690, 255 N. W. 414 (1934); *Cushing v. Rodman*, 65 App. D. C. 258, 82 F. (2d) 864 (1936); *DeHaan v. Winter*, 258 Mich. 293, 241 N. W. 923 (1932); *DeGroot v. Winter*, 261 Mich. 660, 247 N. W. 69 (1933).

[8] Reed Dickerson, *Products Liability and the Food Consumer* (1951); Mr. Bradshaw Mintener, vice president and general counsel for Pillsbury Mills, Inc., reports on developments, frequently, to the annual meetings of the Section of Food, Drug and Cosmetic Law of the New York State Bar Association and of the Division on Food, Drug and Cosmetic Law in the Section of Corporation, Banking and Business Law of the American Bar Association. His reports are published in the FOOD DRUG COSMETIC LAW JOURNAL, as follows: Vol. 1, No. 1, March, 1946, p. 96; Vol. 2, No. 1, March, 1947, p. 62; Vol. 3, No. 1, March, 1948, p. 76; Vol. 4, No. 1, March, 1949, p. 110; Vol. 5, No. 2, April, 1950, p. 168; Vol. 5, No. 9, November, 1950, p. 764; Vol. 6, No. 3, March, 1951, p. 225; Vol. 7, No. 7, July, 1952, p. 466. CCH FOOD DRUG COSMETIC LAW REPORTS—section on product liability contains commentary with annotations with full reports of currently decided product liability cases. 36 CJS 1101, and following; 22 Am. Jur. 876, and following; Melick, *The Sale of Food and Drink* (Prentice-Hall, 1936); Williston on Sales, revised edition, Section 241, et seq.

An exploding-bottle case came before the Supreme Court of Michigan in *Macres v. Coca-Cola Bottling Company, Inc.*, 290 Mich. 567, 287 N. W. 922 (1939), and it was held that a bottling company's negligent charging of a bottle of soft drink rendered the company liable in damages. The case contains an excellent discussion of the exploding bottle cases, with extensive citation of authorities and A. L. R. annotations.[9]

A number of pertinent law review articles in the *Michigan Law Review* are cited below.[10]

The foregoing brief review of some of the important phases of the Michigan food laws is by no means exhaustive, but it is hoped that it will be helpful to the Michigan practitioner who is confronted with problems thereunder, as a starting point in his work. **[The End]**

• GRISWOLD BECOMES FOOD LAW INSTITUTE TRUSTEE •

In a letter dated July 28, 1952, addressed to Charles Wesley Dunn, President of The Food Law Institute, Inc., Erwin N. Griswold wrote as follows:

"Dear Mr. Dunn,

"Thank you very much for your letter of July 25 . . . .

"It is good of you to invite me to become one of the public trustees of the Food Law Institute. I am glad to accept, and to be associated with you in this work in that capacity. . . ."

"With best wishes,

Very truly yours,
Erwin N. Griswold
Dean"
[Law School of Harvard University]

[9] See also *Dobrenski v. Blatz Brewing Company*, 41 F. Supp. 291 (DC Mich., 1941). (1941).

[10] "Liability of Manufacturer or Vendor to an Allergic Consumer," Note, 49 *Michigan Law Review* 253 (1950); *"Res Ipsa Loquitur* Not Applicable to Breaking of Beverage Bottle in Hands of Purchaser," Note, 42 *Michigan Law Review* 536 (1943); "Sales—Retail Dealers—Liability for Defects in Canned Goods," Note, 41 *Michigan Law Review* 861 (1943); "Torts—Liability of Food Manufacturer to Ultimate Consumer," Note, 40 *Michigan Law Review* 928 (1942); "Another New Tort?—Liability of Manufacturer of Automobile for Non-negligent Defect," by Paul A. Leidy, 38 *Michigan Law Review* 964 (1940); "Manufacturer's Liability for Injuries Caused by His Products: Defective Automobiles," by Lester W. Feezer, 37 *Michigan Law Review* 1 (1938); "Retail Responsibility and Judicial Law Making," by Professor J. B. Waite, 34 *Michigan Law Review* 494 (1936); "Sales—Warranty—Theory of Implied Assignment," Note, 29 *Michigan Law Review* 906 (1931); "Sales—Implied Warranty of Fitness Under Uniform Act," Note, 29 *Michigan Law Review* 944 (1931); "Sales—Does Implied Warranty Run with Foodstuffs?" Note, 28 *Michigan Law Review* 90 (1929); "Torts—Liability of Vendor for Defective Dynamite Fuse," Note, 26 *Michigan Law Review* 585 (1928); "Sales—Food—Implied Warranty of Fitness—Privity," Note, 26 *Michigan Law Review* 825 (1928); "Sales — Foodstuffs — Does Implied Warranty Run with Chattel?" Note, 23 *Michigan Law Review* 919 (1925).

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the executive branch of the Government for the services of personnel loaned to the committee on a reimbursable basis.

On February 2, 1951, the House agreed to House Resolution 74 (82nd Cong., 1st sess.), which provided:

"That effective from January 3, 1951, the select committee created by House Resolution 323 of the Eighty-first Congress is authorized to continue the investigation and study begun under authority of such House Resolution 323 and for such purposes shall have the same power and authority as that conferred by such House Resolution 323. The committee shall report to the House (or to the Clerk of the House if the House is not in session) as soon as practicable during the present Congress, the results of its investigation and study, together with such recommendations for legislation as it may deem advisable."

House Resolution 128 (82nd Cong., 1st sess.), agreed to February 20, 1951, appropriated $75,000 from the contingent fund of the House to finance the committee's operations. Of this amount, approximately $45,000 will have been expended by the committee at the conclusion of its deliberations. It is estimated that $30,000 will be returned to the contingent fund of the House. Approximately $25,000 of the expended amount will have been paid to the executive branch of the Government for the services of personnel borrowed by the committee on a reimbursable basis.

On October 15, 1951, the House agreed to House Resolution 447 (82nd Cong., 1st sess.), which extended the scope of the committee's authority to include:

". . . an investigation and study of the nature, extent, and effect of the use of chemicals, compounds, and synthetics in the production, processing, preparation, and packaging of cosmetics to determine the effect of the use of such chemicals, compounds, and synthetics upon the health and welfare of the Nation."

Pursuant to the instructions contained in House Resolution 74 and House Resolution 447, public hearings were held during April, May, June, October, and November, 1951, and January, February, and March, 1952. The committee devoted 39 days to public hearings, in which 143 witnesses were heard. During the whole life of your committeee, 59 public hearings were held and 217 witnesses presented their views. These witnesses included representatives of the American Medical Association, American Dental Association, American Public Health Association, New York Academy of Medicine, National Research Council, United States Public Health Service, United States Food and Drug Administration, United States Department of Agriculture, Association of State and Territorial Health Officers, American Cancer Society, Grocery Manufacturers of America, National Canners Association, National Agricultural Chemicals Association, Manufacturing Chemists' Association, National Fertilizer Association, American Plant Food Council, General Federation of Women's Clubs, Cooperative League of the U. S. A., American Home Economics Association, National Council of Farmer Cooperatives, National Grange, and National Farmers Union.

Various other witnesses, representing the chemical industry, the fertilizer industry, the pesticide industry, the food industry, the cosmetic industry, professional groups and consumers' groups, as well as expert witnesses from colleges, universities, and agricultural experiment stations, were also heard.

It has been estimated that over 700 chemicals are presently used in or on foods. It was manifestly impossible for this committee to study exhaustively every phase of food production, or every chemical used in this industry. The chemicals, and phases of food production, which were subjects of more intensive investigation than others, were selected on the basis of their importance to the public health and economy of the Nation.

In the interest of simplicity, your committee proposes to divide the subject matter of its investigation into four sections and prepare a separate report for each section.

The first two reports, submitted on May 12, 1952, and June 17, 1952, were entitled, respectively, "Fertilizers" and "Cosmetics." The third report, which is respectfully submitted, is entitled "Food."

II. Nature and Scope of the Problem

Tremendous progress in the science of food technology has been made in the comparatively recent past. The growth of population, in this country and abroad, has increased the need for greater crop yields of high quality, and this need in turn has resulted in the rapid development of pesticides to combat insect infestations and plant disease. Specialized farming, which makes it necessary to ship crops to distant points, together with the need for long storage periods, has provided an impetus for the introduction of various methods of food preservation. The increasing world demand for a more abundant food supply has accelerated the growing tendency to utilize synthetics not only to enhance food flavor and appearance but, more important, to prevent waste and spoilage.

At this stage of our civilization, there is a genuine need for the use of many chemicals in connection with our food supply. Many of the chemicals directly added to foods have proved to be of substantial value to the consumer, and constitute a necessary adjunct to modern civilization. Few would quarrel now with the advisability of enriching various staple foods with certain vitamins and minerals, or with the addition of other chemicals which enhance the nutritive value of the products in which they are incorporated. The addition of iodine compounds to salt to prevent goiter has proven of real benefit to the consumer in areas where there is an iodine deficiency in the diet. Furthermore, substances added to a food during processing for such functional purposes as discoloration prevention sometimes result in the enhancement of its nutritional value. An example is the improvement in the vitamin C content of frozen peaches when ascorbic acid is added to prevent unsightly browning of the cut fruit.

The American public may feel justifiably proud of the manner in which the scientists of this country, in conjunction with the food and chemical industries, have solved the many serious food problems which have arisen. In the judgment of the committee, the food industry is entitled to considerable credit for the progress of research in the field of nutrition and the practical application of such research. This has resulted in an improvement in the health and nutiritional status of millions. Nevertheless, the public is in need of protection against small, irresponsible elements, as well as against the possible inadvertent mistakes of reputable food processors and premature enthusiams of chemical manufacturers.

The rapid strides in the application of science to the production and processing of food offer great possibilities for the welfare of mankind. The progress that has been made in food technology, however, has been attended by a certain degree of hazard, since some quantity of many of the new chemicals utilized in the production and processing of foods is inevitably ingested by

the consuming public. It is essential that this risk be kept to a minimum.

The number of chemicals entering the food supply of the Nation has increased tremendously in the last decade. Chemical substances are being introduced into the production, processing, storage, packaging and distribution of food at an ever-increasing rate. There is hardly a food sold in the market place today which has not had some chemicals used on or in it at some stage in its production, processing, packaging, transportation, or storage. These foods include those eaten by every family, ranging from staples like bread to such luxury items as the maraschino cherry. Some eminent pharmacologists, toxicologists, physiologists, and nutritionists expressed the fear that many of the chemicals being added to food today have not been tested sufficiently to establish their nontoxicity and suitably for use in food. These scientists are not so much concerned with the acutely toxic compounds, whose harmfulness can readily be detected, as with those chemicals which may produce harmful effects only after being ingested for months or perhaps years.

The indirect addition of chemicals to our food supply also raises serious problems. For example, cattle are being treated with antibiotic drugs in the control of mastitis, anthrax, and other diseases. There is a question whether the presence of small amounts of antibiotics in milk and milk products has any effect on the consumer; that is, whether the consumer develops a sensitivity or resistance to these chemicals. In such cases, the resistant or sensitive individual would be unable to benefit from treatment with these valuable drugs in the event of illness (1).

The United States Food and Drug Administration, in collaboration with the United States Public Health Service, revealed that approximately 842 chemicals are used, have been used, or have been suggested for use in foods. Of this total, it was estimated that 704 are employed today, and that of these 704 only 428 are definitely known to be safe. Thus, there are approximately 276 chemicals being used in food today, the safety of which has not been established to the satisfaction of many groups concerned with the health and safety of the public (2).

The Surgeon General of the Public Health Service pointed out that the extent of this problem cannot be fully visualized, because of a lack of adequate information on the chronic effects of chemical substances currently in use. He testified that the toxic effects of many of these chemicals, and of the compounds which they form when introduced into food, are unknown. He expressed concern over the possible adverse effects which chemicals used in food products may have upon human health (3).

The American Public Health Association has stated that the toxicologic properties of many of the chemicals used in the production and processing of foods, especially the chronic effects of their long-time consumption, are not known. The Council on Foods and Nutrition of the American Medical Association has described the increasing use of chemicals in food as a potential health hazard which may become one of the greatest problems the food industry has ever had to face (4). The situation was outlined by the Commissioner of the Food and Drug Administration as follows:

"It would be both unfair and incorrect to appraise this problem on the assumption that we have an irresponsible chemical industry and an irresponsible food industry, both callous to the health of consumers. Nor can we appraise it on the assumption that this is just a bureaucratic grab for dictatorial powers over the food and chemical industries. The facts belie both assumptions; but the facts show that there is a fringe of the careless or ignorant or unscrupulous who have

used or are now using chemicals in food without sufficient testing to be reasonably certain they will not impair the health of consumers. We have seen insecticides marketed before toxicity tests were made, other than those required to show the LD_{50}, and before adequate quantitative analytical methods were developed. We have seen the paradox of vigorously pressed sales campaigns for chemical additives while tests to discover unknown facts about their toxicity were being planned or carried out.

"That the dramatic equivalent of the elixir sulfanilamide disaster of 1937 that cost more than a hundred lives has not occurred in the food field speaks volumes, first, for the conscientiousness of these industries generally, and second, for the providential luck of the fringe operators—and of the public. We have had some narrow escapes." (5)

One problem which is causing scientists increasing concern is the possible effect of various synthetic substances in the production or acceleration of cancerous growths. The testimony proffered was not that certain chemicals presently in use as additives and insecticides do cause cancer, but rather that there is a definite lack of knowledge on the subject (6). The head of the Nutrition Unit in the Biochemistry Section of the National Cancer Institute set forth the situation in the following language:

"In summary, I have pointed out: (1) That a large number of chemical compounds induce cancer in animals. (2) That there is no way of predicting their cancer-inducing properties without a biological test. (3) That the careful testing of chemicals for cancer-producing properties in animals is exceedingly difficult to evaluate. Any test for cancer is influenced by a very large number of environmental and hereditary factors which the experimenter must seek to control and evaluate. I believe any estimate of the possible injurious properties of chemicals added to nutrients consumed by men should include careful testing for their carcinogenic properties in several species of animals prior to approving their use in food." (7)

Nor is the problem confined to inadequately tested insecticides or other chemical substances added to foods. Paper, fiber, and plastics are becoming increasingly popular as food containers and food-handling equipment. These, together with the use of chemicals in wrappers, may create a hazard to health. It is obvious that the toxicity and potential danger of these materials should be studied before their use in the food industry is permitted.

In addition, although many chemicals, as already indicated, serve a useful purpose to the consumer, others do not and may in fact conceal inferiority, adversely affect the nutritive value of the foods in which they are employed, or act as substitutes for nutritous ingredients (8).

The committee wishes to point out that the United States Food and Drug Administration, the United States Public Health Service, the United States Department of Agriculture, as well as comparable State agencies, industry and colleges and universities, are devoting considerable time and sums of money to research and experimental work for the purpose of obtaining solutions to these problems.

III. The Use of Chemicals in the Production, Processing, Preservation, and Packaging of Foods

There is nothing objectionable per se in the introduction of chemicals in the production, processing, preservation, and packaging of foods (9). However, some chemicals have been employed which proved harmful or which were utilized before their harmfulness had been established. A few of these will be discussed.

NITROGEN TRICHLORIDE

Nitrogen trichloride, commonly referred to as Agene, was employed for approximately 30 years in the flour-milling industry. It was used primarily to age artificially certain types of flour. In 1946, an English investigator discovered that dogs fed bread baked from flour treated with nitrogen trichloride developed canine hysteria, commonly referred to as running fits. Experiments by qualified investigators in this country soon confirmed these results in experimental work on dogs as well as other animals, but they were not able to establish any injury to humans. The baking industry and the manufacturer of Agene agreed that it should not be employed in flour, whereupon a hearing was held by the Food and Drug Administration and such use was prohibited (10).

THIOUREA

In 1946, a chemical known as thiourea was proposed for use on citrus fruit to prevent a certain kind of mold. Before it was so employed, the persons proposing its use consulted with the Food and Drug Administration. Experiments were conducted which showed that thiourea, in addition to being very poisonous, penetrated the skin of citrus fruits and found its way into the juice. As a result of these investigations thiourea was never used on citrus fruits, but several shipments of frozen peaches containing the substance were seized and destroyed. Less cautious food manufacturers might have proceeded to use it, as permitted under existing law, without consulting with the Food and Drug Administration and before determining the toxic properties of the substance, as in the case of the manufacturer of the frozen peaches. Were it not for the fact that all of the contaminated peaches were seized before they had reached the consumer, a serious poisoning episode might have occurred (11).

PARA-PHENETYL UREA

Para-phenetyl urea is a sweetening agent which was used for over 50 years as a sugar substitute for diabetics and others. Until the Food and Drug Administration undertook a chronic toxicity study of this substance several years ago, no investigation of its possible toxic effects, when ingested in small amounts, over an extended period of time, had ever been made. Results of the experiment revealed that para-phenetyl urea is poisonous under such conditions. One firm continued to use it in its food products even after being warned of its toxicity. At that time, action could not be taken against the firm because the toxicity studies had not been completed (12).

LITHIUM CHLORIDE

A salt substitute containing lithium chloride was marketed several years ago for persons required to be on a low-salt diet. Subsequently, it was discovered that the substance is extremely poisonous for persons who have been on such a diet for some time, so that the salt content of the body has been reduced. Action was taken immediately and preparations of salt substitutes which contained lithium chloride were removed from the market, but several deaths had occurred (13).

MINERAL OIL

Mineral oil was long regarded as harmless. It had been used in a variety of special dietary foods, particularly salad dressing, as a substitute for food oils. Between 1941 and 1945 evidence became available which showed that mineral oil, when taken with foods, interferes with the absorption of various vitamins. As a result of this evidence, mineral oil is no longer permitted as a food ingredient (14).

MONOCHLORACETIC ACID

Monochloracetic acid was used by a number of food manufacturers as a food preservative. Experimental work

performed by the Food and Drug Administration revealed that the substance had an acute toxicity comparable to such recognized poisons as bichloride of mercury, carbolic acid, and strychnine. The Food and Drug Administration then announced that the acid must be regarded as a poisonous and deleterious substance which should not be used in food products. Notwithstanding this, many foods containing monochloracetic acid were subsequently placed on the market. In one instance, a synthetic orange-type beverage containing the substance was distributed widely in the South and caused extensive digestive upsets of a very acute type (15).

DEHYDROACETIC ACID

In March of this year, the Food and Drug Administration seized more than 6,000 pounds of cheese because it was enclosed in a newly developed wrapper containing dehydroacetic acid, which transfers from the wrapper to the cheese and is readily absorbed in it. The chemical had been used to prevent the growth of mold on the cheese, and was odorless and colorless. The Food and Drug Administration has declared that dehydroacetic acid has the toxicity of carbolic acid (16).

EMULSIFIERS

During the past 14 years, a number of substances referred to as emulsifiers or surface-active agents have been used in a wide range of foods. The emulsifiers fall into four main categories: (I) mono- and di-glycerides of fat-forming fatty acids, which are formed by reacting glycerin with fat; (II) a class of compounds produced by reacting sorbitol, a sugar alcohol, with a fatty acid; (III) a class of compounds produced by reacting a sorbitan ester of a fatty acid with polymerized ethylene oxide; and (IV) polyoxyethylene monostearate, which is prepared by reacting polymerized ethylene oxide directly with a fatty acid, or by first reacting ethylene oxide with water to form a glycol and then reacting the polymerized glycol with a fatty acid. By varying the fatty acid and the length of the polymerized ethylene oxide chain, a great many compounds may be made in each class (17).

In 1937, it was found that when small amounts of mono- and diglycerides are mixed with shortening and the shortening incorporated into baked goods, their use resulted in what has been described as "more tender" bread, buns, cake, and other sweet goods. Thereafter, shortenings containing varying amounts of mono- and diglycerides were marketed. Subsequently, it was ascertained that, by increasing the ratio of mono- and diglycerides in shortening, a very soft loaf of bread could be produced. In 1947, when the polyoxyethylene monostearate type of bread softener appeared on the market, superglycerinated shortening and polyoxyethylene monostearate became competitive products in the baking industry. Thus, the name "bread softener" has come to mean preparations containing either mono- and diglycerides or polyoxyethylene monostearate. In addition to their use in shortening, mono- and diglycerides are used as emulsifiers in prepared cake mixes and in the ice-cream industry, where they compete with the polyoxyethylene monostearate type of emulsifier.

Mono- and diglycerides are said to occur in small quantities in some natural fats, and are present in small amounts in the animal intestine during the digestive process, but heretofore they have not been ingested in amounts comparable to the amounts being added to some shortening.

The principal food uses of the types of emulsifiers referred to above as classes (II) and (III) are in prepared cake mixes, baked goods and ice cream. They are also utilized to some extent as dispersing agents in flavors, essentail oils and polyvitamin solutions. The last main class of emulsifiers, polyoxyethylene monostearate, referred to

above as class (IV), is employed primarily in the bread industry as a bread softener. At the hearings held by the Food and Drug Administration to prescribe definitions and standards of identity for bread, rolls and buns, certain of these three classes of emulsifiers were proposed for use in bread and the results of a large number of experiments with these categories were presented. A large part of the hearings was devoted to the presentation and interpretation of this data. The Administrator of the Federal Security Agency has issued a regulation which contains a finding of fact that the evidence is not sufficient to warrant the conclusion that there is no likelihood of injury from bread containing the substances comprising groups (II), (III), or (IV), if ingested continuously over the human life span (18).

On November 9, 1951, the Food Protection Committee of the National Research Council announced that it had made a study of the experimental data on both the mono- and diglycerides and the polyoxyethylene type of surface active agent proposed for use in foods. Its opinion was that the available data "on the toxicity, tolerance, metabolic fate, and nutritive value of these surface active agents proposed for use in ice cream are insufficient to permit a final judgment as to the safety of the substances for use in foods." (19)

These substances are being used in tremendous quantities and have been incorporated into many of the basic foods eaten every day, notwithstanding that there is a definite controversy among reputable scientists as to whether the compounds are safe for use in food. Adequate and comprehensive experimentation and research may reveal that they do not present a danger to the public. It is clear, however, that some of these compounds, at least, were injected into the Nation's food supply without sufficient testing to insure beyond a reasonable doubt that their use did not create a long-range health hazard (20).

As early as July 2, 1949, the Council on Foods and Nutrition of the American Medical Association issued an official statement on the use of the chemical emulsifiers in food. This statement said in part:

"Available knowledge of the possible toxicity of these substances is fragmentary; particularly is evidence lacking as to chronic toxicity. The employment of these agents in the processing of such basic foods as bread and bakery goods, as well as other foods (such as ice cream, candy, and peanut butter), could lead to the ingestion of considerable quantities of these materials of uncertain toxicologic action. Unless the complete harmlessness of these agents can be demonstrated beyond a reasonable doubt, they should not, in the council's opinion, be employed in basic foods." (21)

A representative of the American Medical Association testified that chemical additives may permit the lowering of the proportions of important food ingredients in the product and thereby result in a dilution or deterioration in nutritive value of the food, and recommended that:

"Intentional chemical additives, especially those likely to find their way into basic foodstuffs or to find widespread application in a variety of foods, each of which may be infrequently eaten, must not be permitted until the complete harmlessness of these agents can be demonstrated beyond reasonable doubt. Furthermore, the use of additives which lead to a significant decrease in nutritive value should not be permitted." (22)

This viewpoint on safety testing is similar to the position taken by the Food Protection Committee of the National Research Council in a release issued on December 11, 1951, entitled "Use of Chemical Additives in Foods," that "chemical additives should not be permitted in a food until their safety for a given food use has been established beyond a reasonable doubt, as

judged by competent experts." Your committee is also of the opinion that the best interest of the public health requires that the manufacturer of a chemical proposed for use in or on any food, or a food manufacturer who develops such a chemical, should submit evidence to the satisfaction of the Food and Drug Administration that the chemical is safe for use, as far as the end food product is concerned, from both an acute and chronic viewpoint. There have been no reported deaths due to the ingestion of foods containing untested chemicals. The Commissioner of the Food and Drug Administration testified, however, that we have had some narrow escapes. This was in accord with the views of the Director of the Bureau of Nutrition of the Department of Health of New York City, testifying on behalf of the New York Academy of Medicine, who stated:

"I would hazard a guess, Mr. Counsel, that with the rapid expansion of the chemical industry—and, frankly, many people including myself think we are only at the beginning of the growth and usefulness of this industry—that without very definite regulation a similar tragedy may occur, and it may be a far worse one than the sulfanilamide tragedy, because these chemicals will be put in the food that will be more widely used and consumed than, say a drug that is used only for sick people." (23)

As previously indicated, it is heartening that various Federal and State agencies, as well as industry and scientific groups, are devoting themselves with the utmost diligence to research directed at the protection of the public health. The committee recommends that such activities in this vital field be augmented.

HORMONES IN FOOD PRODUCTION

The use of hormones and other similar substances for the purpose of improving the quality, and perhaps in some cases the quantity, of food has opened an entirely new field in food technology which may prove to be of great benefit to the consumer. At present, Government, industry and scientific groups are continuing their research and experimental work in this field to determine to what extent these preparations may be employed, and whether there is any hazard to the public health from these practices. The committee urges that such research in this important field be expanded.

The aspect with which the committee was particularly concerned was the use of diethylstilbestrol to fatten and tenderize poultry and livestock. It is estimated that in 1950 this chemical, in 15-milligram pellets, was used on approximately 30 million chickens, and its use is reported to be increasing.

Diethylstilbestrol is a synthetically produced chemical having activity very similar to the natural female sex hormones. Directions for use call for the implantation of one pellet into the upper region of the neck of the bird, at the base of the brain, about 4 to 8 weeks prior to marketing, during which period the chemical is slowly absorbed into the system of the bird. Male birds so treated rapidly lose many male characteristics; combs, wattles, and reproductive organs shrivel; and the propensity for crowing and fighting disappears. The flesh of birds so treated contains greater deposits of fat than the flesh of nontreated birds. This results in a heavier bird, with meat that is said to be more tender and of smoother texture, although there was testimony that the fat of fowl treated with stilbestrol differs chemically from that of normally fattened birds and is watery and inferior culinarily. Treated birds command a premium price on the market, and have been called "caponnettes" or "hormonized fryers." The results secured by this process are very similar to those obtained by surgically castrating the male bird, a procedure which has been in use for many years. The increasing popularity of the chem-

ical method is due, for the most part, to the convenience of administration, for which no special training is needed. A mechanical injector, similar to a hypodermic syringe, implants the pellets quickly and efficiently just below the surface of the skin (24).

Diethylstilbestrol is a potent and dangerous chemical, which cannot be purchased in drug stores for medical purposes without a physician's prescription. It is used extensively by the medical profession to alleviate menopausal difficulties and dysmenorrhea, and to suppress lactation and excessive uterine bleeding. It has also been employed to ease the pain of prostatic cancer because of its action in shrinking the male sex organs, thus reducing the pressure on the cancer. Stilbestrol has been shown to inhibit the growth of young rats and chicks, and has been used to prevent excessive tallness in girls (25).

The human body, female and male, requires and produces, for normal operation, quantities of both the female sex hormone (estrogen) and the male sex hormone (androgen). Among other things, these hormones determine and affect certain of the sex characteristics of the individual. Thus, proper quantities and proportions of these hormones may affect, among other things, sex drive, development of sex organs, breast development, quantity of facial and body hair, height, voice pitch, and the like. An imbalance of significant proportion between the male and female sex hormones in the body will result in the individual's acquiring some of the physical characteristics of the opposite sex (26).

Very few data have been published concerning the quantity of stilbestrol which may be found in the edible tissues of a treated bird. No one can state with any assurance just how much of this material remains in the tissue, although it was testified that the quantity is very small (27). There is practically no information concerning the effects of the long term ingestion of minute quantities of stilbestrol (28). The testimony of scientific experts concerning the safety of ingesting the flesh of stilbestrol treated poultry is in conflict (29).

Because of the tendency of living tissue to wall off foreign bodies, there is always the possibility that stilbestrol pellets will be isolated and not completely absorbed into the tissue of the chicken. In addition, a residual pellet will remain in the carcass if the bird is marketed prior to the expiration of the absorption period of 4 to 8 weeks. For this reason, and because it is generally agreed that the ingestion of portions of a diethylstilbestrol pellet may result in adverse physiological effects, directions for use of this material require the site of implantation to be high on the neck at the base of the skull, so that on slaughtering, the site of implantation will be removed and thrown away as the chicken head is severed (30).

Recently, the United States Food and Drug Administration sampled several lots of stilbestrol-treated chickens which had been shipped in interstate commerce. Examination showed that 60 percent of the sampled chickens contained portions of unabsorbed stilbestrol pellets in areas of the neck which would remain with the consumer after normal severing of the head from the carcass. Prompt legal action followed, and approximately 50,000 pounds of stilbestrol-treated chickens were seized and condemned (31).

It is obvious that the Food and Drug Administration, with its small staff of approximately 250 field inspectors to cover the entire country, cannot possibly hope to sample and examine every interstate shipment of food, drugs, and cosmetics. Inevitably, of course, many shipments of foods must traverse State lines without any examination. Where a potentially dangerous chemical substance is utilized in such a manner that only the user is exposed to harm if he ignores or abuses the directions for safe use of such material, little can be done

by way of protective legislation or regulation except to require clear, explicit directions which permit safe usage. This is the case with medicine or drugs. The few who would experiment with their own health by ignoring the recognized or prescribed directions for use can harm only themselves. However, in situations where an individual's abuse or disregard of directions for use of a potentially dangerous substance may adversely affect the health of innocent consumers, as in the case of stilbestrol-implanted poultry, regard for the public health requires the application of different rules of policy. Evidence of widespread abuse of directions for use in situations of that nature should be sufficient to forbid the use of the chemical for such purposes.

Recent experimental evidence, showing, among other things, that milk production and the weight of livestock can be increased by the administration of estrogen and other chemical substances may well complicate this problem (32). The adoption of such practices among livestock raisers may result in an increment of estrogen and estrogen-like substances in the dietary of the average consumer.

The committee is of the opinion that the meat of poultry or other animals which has been treated with estrogens be labeled so as to reveal that fact, and that restaurants serving such estrogen-treated food be required to advise customers to that effect.

IV. The Use of Pesticides

It is generally agreed that many food crops cannot be brought to complete and fully satisfactory maturity without the use of pesticides. It is also recognized that many of the chemicals used as pesticides are very toxic, and that great care must be exercised to prevent harmful residues from remaining on foods when they are marketed.

With the advent of the newer organic pesticides following World War II, the use of chemicals having pesticidal action increased markedly; and it is estimated that there are approximately 100 pesticidal chemicals now in use, and that over 30,000 pesticidal formulations have been registered for labeling and use by the Insecticide Division of the United States Department of Agriculture (33). The expansion in the use of pesticides has created serious problems. One of the disturbing things about the advance in insecticide use, and the discovery of new insecticides, was that many such substances were put into use although very little was known with respect to either their acute or chronic toxicity or about their fate after they were applied to food (34). In 1948, the Council on Foods and Nutrition of the American Medical Association declared that the appearance of the new insecticides had created a danger; that there was an appalling lack of factual data concerning the effect of these substances when ingested with food; and that the chronic toxicity to man of most of the newer insecticides was entirely unexplored (35). Subsequently, on January 28, 1950, the Council on Foods and Nutrition stated, in part:

"The introduction of numerous synthetic organic pesticides offers promise for increasing the Nation's food supply and improving health through the control of insects and other pests. Past experience, however, indicates that poisons cannot be used safely on food crops without the development of certain fundamental knowledge concerning the poisons. What these materials will do to pests and food crops and to workers who handle them must be known, and there must be developed, also, a knowledge of what these materials will do to warm-blooded animals and man when small amounts of residue are incorporated in their foods. Furthermore, practical methods of analysis should be available to permit identification and measurement of residues that may persist on or in consumer products. Such essential information is undeveloped for

many of the agricultural poisons now in use." (36)

DDT

DDT, the first of the chlorinated hydrocarbon insecticides, became available in quantity in the United States during World War II. Toxicological work was carried on by representatives of the Government, who reached the conclusion that it was a reasonably calculated military risk to use DDT as a typhus and malaria preventive, and that as a sound military expedient the danger of injury to the troops was far less than the danger from such scourges (37). Shortly thereafter, growers began to use DDT on a variety of food crops, although there was little or no information available on the effect of the long-time ingestion of small quantities and its storage in body tissues (38).

As experience was acquired, the Food and Drug Administration found that DDT is absorbed and stored by the body in the fatty tissues, and that, if an animal is exposed to it for any length of time, it may accumulate there to a degree which will injure the animal. Toxicity tests showed that DDT can be stored at very low levels of intake, and its concentration in the body fat is magnified from 6 to 28 times the dietary intake; that a level of 5 parts per million in the diet of rats produced slight but definite liver injury; and that the rate of disappearance of DDT from body tissues is slow (39).

Subsequent to the widespread use of DDT in dairy barns and on cattle, it was shown that cows sprayed with DDT, or fed silage sprayed with it, or even housed in a barn in which it was sprayed, would accumulate DDT in the fat and eventually secrete it in the milk (40). Although the scientific literature revealed, as early as August 1945, that the milk of lactating dogs receiving DDT contained appreciable levels of the compound, it was not until March 1949, that a governmental warning was issued advising that DDT should not be used on dairy cows or in dairy barns (41).

Years of continuing research have provided a great deal of information, and much more is known now about DDT than when it was first introduced for agricultural use. Nevertheless, there is still sharp disagreement among the experts concerning the hazards associated with its use. On the one hand we are told that it is among the safest of insecticides, and on the other hand that its toxicity has been greatly underestimated (42).

It is apparent that many important questions are still unanswered. As late as March 10, 1951, the committee on pesticides of the American Medical Association reported that—

"Chronic DDT poisoning may result from the ingestion of small amounts of the material over a long time. Since the chemical is irregularly absorbed, the level below which adverse long-range effects are absent is unknown." (43)

Nor is the maximum quantity of DDT which can be taken every day with safety known (44). Scientists are still trying to determine the role of DDT in the metabolism of human fat and its practical relationship to the total health of man, whether DDT storage in human fat causes cellular injury or interferes with the chemistry of the cell, and whether stored DDT, if released into the system, will cause injury (45).

There is conflicting evidence concerning the DDT content of foods normally consumed by the public. It is clear, however, that DDT may be found at times in meat, milk, and other foods eaten by the public (46). The United States Public Health Service, concerned over the possible hazards of DDT residue on food and their effect upon consumers' health, collected human fat samples from volunteers and found that the DDT content of the tissue ranged from zero to 68 parts per million and averaged 5 to 10 parts per million (47). Analysis of human fat samples for DDT

made by the Food and Drug Administration showed an average concentration of 5.3 parts per million. Since all fat samples were taken from persons having no unusual exposure to DDT, it may be inferred that this insecticide is being stored in the tissues of the general population. Analysis of samples of human milk by the Food and Drug Administration disclosed an average concentration of 0.13 part per million. As yet, notwithstanding the extremely widespread use of DDT, clinical data are not available to assess whether or not danger may be associated with its storage in human fat (48).

Some witnesses took the position that the lack of reported deaths due to DDT is sufficient evidence of its excellent record of safety (49). In this connection, your committee accepts the view stated in May 1950, by the Food and Nutrition Section of the American Public Health Association:

"Mortality records alone would seem to show that accidental deaths from toxic chemicals of all kinds are an insignificant part of the total causes of death. The toxicologic properties of many of the chemicals used in the production and processing of foods are unknown, especially the chronic effects of their long-time consumption in foods. Mistakes in judgment about the health qualities of chemicals introduced in foods may adversely affect the health of great numbers of persons. Just as fire prevention is an important part of the control of damage by fire, so also the effective control of chemicals introduced in foods may serve to prevent mass poisoning of the population. It does not seem that the consideration of preventive measures in this field should demand impressive statistics from the death records in order to justify the undertaking." (50)

CHLORDANE

Chlordane is another of the chlorinated hydrocarbon insecticides which has been recommended for use in the household and on a variety of fruit and vegetable crops. It was first made available for commercial usage in 1947, and it has been used extensively. The Director of the Division of Pharmacology of the Food and Drug Administration testified that from a chronic viewpoint chlordane is four to five times more toxic than DDT, that it is stored in human fat at a much faster rate than DDT, and that he would hesitate to eat food that had any chlordane residue on it whatever. He stated that chlordane has no place in the food industry where even the remotest opportunity for contamination exists, and that it should not be used even as a household spray or in floor waxes. Food and Drug Administration tests show that pigeons have been unable to survive in a small room treated with chlordane, even after a thorough scrubbing with alkali and subsequent airing for several weeks. The American Public Health Association has stated that a study of the pharmacology of chlordane showed that degeneration of the liver and kidneys of experimental animals occurred as a result of chronic poisoning (51).

Chlordane is presently being employed on some food crops, and is being recommended for fly control in barns and other places on the farm, except inside dairy barns and milkrooms (52). Furthermore, United States Department of Agriculture Farmers Bulletin No. 2009, "Storage of Small Grains and Shelled Corn on the Farm," issued in September 1949, and in current use during the course of the committee's investigation, recommends the use of chlordane for treating bins for storing small grains and shelled corn. However, representatives of the Insecticide Division of the United States Department of Agriculture testified that if a label were presented for registration recommending chlordane for use in storage bins for grains, such a label would be refused registration. The substance of their testimony in this regard was that no one had consulted with them on the advisability of recommending chlordane

for such a purpose, and if anyone had, the Insecticide Division would have been opposed to such recommendation (53).

SELENIUM

Selenium is an elemental metal which, in the form of selenium compounds, has been used as an insecticide. Animal experimentation has shown that 3 parts per million of selenium in the diet will produce cirrhosis of the liver and that, if feeding is continued, the animals may develop cancer of the liver. The residue remaining on fruits or vegetables sprayed with selenium compounds is rather high. For example, on an unwashed apple it may be as much as 1 part per million, and since it will penetrate the skin it may accumulate in the apple in amounts up to 3 parts per million. The hazard is increased by the fact that selenium builds up in the soil, and can migrate from the soil into the growing plant and eventually appear in the fruit or vegetable (54).

A representative of the Food and Drug Administration declared that selenium should not be used as an insecticide (55). The Assistant Chief of the Insecticide Division of the United States Department of Agriculture testified that, if selenium had not been in use prior to the enactment of the Federal Insecticide, Fungicide, and Rodenticide Act of 1948, and had been proposed for insecticidal use for the first time after the enactment of that statute in 1948, "it probably would not have been registered." (56)

PHENYLMERCURY COMPOUNDS

Phenylmercury compounds are used quite extensively on fruit and vegetable crops as fungicides. Investigation of these compounds shows that they accumulate in the kidney and are very poisonous. Very small quantities taken into the body lead to measurable storage in the kidney with resulting damage to the organ. Although phenylmercury compounds may be used safely on some foods if the foods are carefully cleaned after harvest to remove residues, the order of toxicity of these substances is so high that it has been suggested that their use not be permitted on foods under any conditions (57).

BENZENE HEXACHLORIDE

Benzene hexachloride, originally thought to be relatively harmless to higher animals, now is known to have toxic properties similar to those of DDT, differing, however, in that benzene hexachloride appears in the brain tissue of the experimental animals to which it has been administered (58). Farmers and canners have suffered considerable financial loss because of off-flavors resulting from the use of this substance on various crops. It was testified that benzene hexachloride tends to penetrate into the edible portions of some crops; that, due to its penetrating effect, no procedure has been developed which will completely remove residues or off-flavors resulting from its presence; and that processing in many instances tends to accentuate the off-flavor. It was also testified that benzene hexachloride residues may remain in the soil for several years, and under certain conditions of continued application may tend to accumulate and produce off-flavors in subsequent and different crops grown on the same soil (59).

The above illustrations present some examples of the hazards which may arise from the use of pesticides in or on foods. There are other pesticides presently in use or proposed for use whose safety has not been established. In some cases, toxicological and pharmacological studies have not been sufficient to establish their safety as recommended for use. In other instances, no reliable practical methods of analysis for the chemical or its breakdown products are available to determine the amount of harmful residue which may remain in or on the food. Obviously, such information is essential for the protection of both the public and the food processor and canner (60).

One of the country's larger food-processing companies, specializing in food for infants, pointed out that many of the insecticides were introduced solely on the basis of their insect-control efficiency. A representative testified that it was costing this company at least $100,000 every year in attempting to keep pesticidal residues out of its food products. He stated:

"Most of the difficulties with residues, which we have described, have been due to their general use before sufficient scientific information was available on residue stability, residue penetration, development of off-flavors in fresh or processed foods, their accumulation in soils, their effect on the over-all insect population, or the development of resistance in certain species of insects. The disturbed ecological relationships, which have often destroyed beneficial predatory insects, have allowed the build-up of other insect pests, which could not be controlled by normal spray procedures; this, combined with the development of resistance to specific insecticides, has resulted in control programs which have caused the build-up of excessive residues in the hope of achieving control, and when this was unsuccessful, the hasty and often ill-advised use of new and more effective insecticides which had not yet been thoroughly tested. The net result has often been the creation of residue or off-flavor problems more serious than those arising from the use of the original insecticide." (61)

This was borne out by testimony from the former Commissioner of the Food and Drug Administration, who described the situation as follows:

"One of the disturbing things about the recent advance in insecticides, in the discovery of new insecticides, has been that a great many very potent and valuable insecticides have been developed about which very little is known, either about their chronic or acute toxicity or about their fate after they are applied to food. In many cases we do not know whether the insecticide after application is absorbed into the body of the food, whether it is destroyed on weathering, whether it degenerates, perhaps, into some more toxic substance. There were even insecticides put out for which no chemical method of identification or analysis is known." (62)

Satisfactory analytical methods of residue analysis are presently not available for many commonly used pesticides, such as chlordane, toxaphene, aldrin, dieldrin, and heptachlor (63).

A complicating factor in the evaluation of the use of pesticides is the tendency of some pesticides to accumulate in the soil, remaining there, in some cases, for many years, and contaminating other crops grown during that period (64). Thus, the use of chlordane in the soil or on growing crops may result in its presence in the soil, in a relatively unchanged form, for at least a year (65). There is evidence that because of the great persistence of the toxicity of DDT, and its relatively high toxicity to many crops on the mineral soils on which it has been tested, residues harmful to the soil may accumulate under some conditions of use in as short a period as 3 to 5 years (66). Contamination, disagreeable odors and off-flavors of many food crops have resulted from pesticide penetration or its translocation from the soil to the plant (67). Many pesticides have been released for use before this type of information was available (68).

There is one aspect of this important problem which is encouraging. Some States have comprehensive laws and regulations dealing with the use of pesticides. The United States Department of Agriculture, the United States Food and Drug Administration, and the United States Public Health Service are conducting vital experimental work in this field. State agencies and universities and agricultural experiment stations are also carrying on exhaustive research. And industry is spending large sums of money in attempting to

develop newer and more effective pesticides which are harmless to the applier, to crops and livestock, and to the consuming public.

V. The Use of Chemical Emulsifiers To Replace Natural Food Substances in Baked Goods

Chemical emulsifiers, which have been discussed earlier, are being used in appreciable quantities, and have been employed not only in commercial bread, but in cake, prepared cake mixes, ice cream, and many other foods. In most instances, the type of emulsifier is not indicated on the label of the food in which it is contained. Approximately 10 million pounds of the chemical softeners are employed in food products each year, at a cost to food manufacturers of several millions of dollars.

The commercial baking industry, with its production of bread, rolls, cakes, and other sweet goods, is a very important outlet for many agricultural products in addition to wheat flour (69). There are no reliable statistics on the composition of commercial bread, on the amounts of shortening and other ingredients used in its production, or on the reduced use of any ingredients resulting from the employment of chemical emulsifiers. Analyses of samples of bread provide data only on the composition of the samples at the time they are collected. Such surveys as have been reported are few in number and of limited extent and value.

Before the war, commercial bread bakers used an average of about 4 pounds of shortening to each 100 pounds of flour. During the war, due to the short supply of fats and oils, bakers were restricted to not more than 2 pounds of shortening to each 100 pounds of flour used in the production of bread. Since the end of the war, the supply of fats and oils has again become plentiful, restrictions have been removed, and some bakers appear to be increasing the amount of shortening employed in bread production so that it approaches the higher prewar level.

The Director of the Fats and Oils Branch, Production and Marketing Administration, Department of Agriculture, testified that the only data available from a Government agency concerning the use of shortening in bread production was a study conducted by an official of the Food and Drug Administration of 421 samples of commercial bread collected from various sections of the country in 1949, which showed the total fat content to be about 4.8 percent of the weight of the flour. Since the fat naturally contained in white flour is about 1.5 percent, the added fat level, according to the survey, would be about 3.3 percent of the weight of the flour. It was the opinion of this witness, and that of other witnesses, that the use of chemical emulsifiers permits a reduction of the amounts of shortening, milk products, and eggs which customarily have been employed in bread, rolls, cake, and other bakery products (70). The witness declared:

"The record of the bread-standards hearings contains evidence of distribution among bakers of advertising material advocating the replacement of fats, oils, eggs, and milk, by emulsifiers. The use of such products as components of food may work to the disadvantage of our farm economy by displacing farm products normally used. The record indicates that natural food constituents, such as fats and oils, probably will be reduced in many commercial bakery products if bakers are allowed to employ these emulsifiers." (71)

In order to obtain some information on this subject, your committee invited a limited number of bakers to provide data on their formulas and the actual amounts of ingredients used in one of the postwar years. Useful information was obtained from 22 wholesale baking companies, whose total yearly production of white bread in 1948 or 1949 amounted to more than 2,600,000,000

pounds, or roughly about one-fifth of the total bread production of the industry.

Thirteen of these baking companies made 685,694,686 pounds of bread in 1 year, with 9,047,319 pounds of shortening, 9,996,593 pounds of skim-milk solids, and 971,500 pounds of a commercial brand of polyoxyethylene monostearate as a chemical softening agent. The shortening employed, based on the flour used as 100 percent, was computed to be from 1.2 to 3 percent, with an average close to 2 percent. Only 3 of those 13 companies used more than 2 percent shortening.

A second group of nine large baking companies produced in 1 year 2,005,013,823 pounds of bread, with 37,582,284 pounds of shortening and 40,778,508 pounds of skim-milk solids. No chemical emulsifiers of the polyoxyethylene monostearate type were used by this group of bakers. The shortening, which included some mono- and diglycerides of fat-forming fatty acids, averaged 2.79 percent, with a range of from 0.5 percent to 4.86 percent, based on the weight of the flour used. Percentagewise, the group of bakers who did not employ the chemical emulsifiers in bread production used an average of 41 percent more shortening, and 38 percent more skim-milk solids, than the group of bakers who used the chemical type of bread softener.

When the polyoxyethylene monostearate type emulsifiers were first marketed to the baking industry on a large scale in 1947, the price of shortening was high. Thirteen bakers at the bread hearings conducted by the Food and Drug Administration testified that salesmen for a few of the companies selling bread softeners had informed them that the amount of shortening in their bread could be reduced by the use of polyoxyethylene monostearate. Most of these bakers reduced their shortening about 50 percent when they started to use this surface-active agent (72). Some early advertisements of certain chemical softeners recommended the softeners as substitutes for lard and shortening (73).

Commercial cake manufacture accounts for a substantial proportion of the annual dollar sales of the baking industry. It also accounts for a large proportion of the total use of shortening and egg products by the industry. The use of emulsifiers permits a reduction in the amount of shortening used in commercial cake production (74).

There are no statistics concerning the effect of emulsifiers on the amount of egg products used in commercial cake production. However, there was testimony that a reduction in the fat content will virtually require a reduction in the egg content (75). Historically, the first of the newer emulsifying chemicals sold to cake bakers was offered as a substitute for eggs during the war when eggs were scarce. A synthetic yellow dye could be added to provide the color formerly obtainable through the use of eggs. The utilization of synthetic yellow dye in commercial cake was practiced before the war. There are indications that the use of artificial coloring matter is increased when quantities of whole eggs or egg yolks are reduced in commercial cake formulas.

A single example may be cited of the changes in formula of a commercial layer cake made by one baking company. This company reported that in 1939 its batter for yellow layer cake was made by mixing the following ingredients, in the quantities indicated: sugar, 30 pounds; sirup, 2 pounds; flour, 30 pounds; frozen whole eggs, 15 pounds; synthetic egg-color solution, three-eighth ounce; vegetable shortening, 10 pounds; nonfat dry-milk solids, 2 pounds 8 ounces; salt, 8 ounces; baking powder, 1 pound 8 ounces; flavoring, 4½ ounces; water, 25 pounds. In 1949, this same company made yellow layer cake batter according to the following formula: sugar, 40 pounds; sirup, 4 pounds; flour, 42 pounds; starch, 5 ounces; frozen whole eggs, 9 pounds; synthetic egg color solution, three-fourth ounce; vege-

table shortening, 7 pounds; nonfat dry-milk solids, 4 pounds; salt, 1 pound; baking powder, 1 pound 14 ounces; flavoring, 6¼ ounces; water, 35 pounds; synthetic emulsifier, 8 ounces in 2 pounds of water. On a percentage basis, the cake batter in 1939 contained 13 percent eggs, and 8.6 percent shortening. In 1949, the cake batter contained 6.2 percent eggs, and 4.8 percent shortening, with somewhat less than 0.3 percent of synthetic emulsifier.

The extent of the effect of the use of chemical emulsifiers upon the market for wholesome agricultural products, such as shortening and eggs, cannot be described with certainty. It is impossible, therefore, to assess the economic impact of emulsifiers on the agricultural economy. It may be stated, however, that the availability of synthetic emulsifiers and synthetic coloring matter simulating the color of egg yolk has been a deterrent to a more liberal use of shortening and eggs by the baking industry (76).

The provisions of the Federal Food, Drug, and Cosmetic Act concerned with the labeling of food ingredients do not require a full disclosure of the ingredients or of their percentages or proportions. The statute provides that the labels of foods such as cakes and similar baked goods, for which a definition and standard of identity has not been prescribed by the Federal Security Administrator under section 401 of the act, must list the ingredients contained in such articles; it does not require the label to declare the percentages or proportions of such ingredients. The labels of those foods, such as bread, for which a definition and standard of identity has been prescribed, are not required by the act to reveal either the names of the ingredients or their percentages or proportions.

VI. Inadequacy of Present Legislation

It is generally agreed that pretesting of chemicals to insure their harmlessness before they find their way into the Nation's food supply is a necessity if the public health is to be protected. The inadequacy of existing laws to furnish this safeguard is exemplified by the testimony of representatives of the United States Food and Drug Administration that, of 704 chemicals employed in food use today, only 428 are definitely known to be safe (77).

With few exceptions, the witnesses who appeared before the committee were of the view that existing laws dealing with the use of chemicals in the production and processing of food products are not adequate to protect the health of the consuming public. They testified to the serious lack of scientific data concerning the harmlessness of products used in and on many common and basic foods, and agreed that careful pretesting by competent investigators would greatly minimize the public health hazard from this source.

It is gratifying that important segments of the food industry have been in the forefront in advocating more comprehensive legislation so that the public may be better protected. Representatives of such organizations as the Beech-Nut Packing Co., General Mills, Inc., Pet Milk Co., Swift & Co., and others communicated to this committee their concern regarding the inadequacy of existing law, and urged that remedial legislation be enacted. The general counsel for the Grocery Manufacturers of America summed up the problem as follows:

". . . [The Federal Food, Drug, and Cosmetic Act] is not effective to prevent unsafe chemical additions to food before its sale to consumers. For it only applies to food after its introduction into interstate commerce; it may only reach the injury to a consumer thus sought to be avoided, after it has occurred; and it does not require an indicated advance scientific determination whether a chemical addition to food is safe, which alone can prevent that injury." (78)

Many qualified witnesses recommended that a section generally similar to the new drug section of the Federal Food, Drug, and Cosmetic Act be added to the statute. This would require that proof of safety of a proposed chemical additive be submitted to the Food and Drug Administration before the chemical is permitted to be used in or on a food product (79). The former Commissioner of the Food and Drug Administration took the position, similar to the viewpoint advocated by many of the other witnesses before the committee, that:

"I firmly believe, gentlemen, that the public interest and the interest of honest manufacturers require that an amendment to the food chapter of the law, quite comparable to the new drug section, be passed by the Congress.

"I feel that no new chemical or no chemical that is subject to any question as to safety should be employed until its possible injurious effect, both on an acute and on a long-time chronic basis, has been shown to be nonexistent. In other words, any chemical that is proposed for use ought to be proved in advance of distribution in a food product to be utterly and completely without the possibility of human injury." (80)

A number of witnesses suggested that an advisory board be appointed to assist the Food and Drug Administration in determining the safety of a chemical proposed for use in a food (81).

The new drug section was enacted as a result of a considerable number of deaths resulting from the sale of untested drug products. One manufacturer, who wished to distribute sulfanilamide in liquid form, added diethylene glycol to the drug as a solvent Diethylene glycol, which is the main ingredient in an antifreezing agent employed in refrigerating systems, is a deadly poison. Without testing the possible toxicity of the mixture, 240 gallons were put on the market. Its use resulted in more than 100 deaths. Shortly thereafter, several deaths occurred from a so-called cancer serum made from pieces of meat which had become contaminated with tetanus organisms (82).

This section prohibits the distribution of a new drug in interstate commerce unless the Federal Security Administrator is satisfied, on the basis of evidence submitted by the party sponsoring the use of the new drug and other available evidence, that it is safe for use as recommended in its labeling. Approximately 8,400 new drug applications have been filed since 1938, of which about 5,850 have been approved. Almost all of the remaining 2,500 applications were found to be based on incomplete data or to pertain to products which were not in fact new drugs, or were voluntarily withdrawn by the manufacturer after the Food and Drug Administration had determined that evidence of safety was insufficient. Only 11 applications were formally rejected, and only 1 such rejection resulted in an appeal by the manufacturer to a United States district court, which sustained the decision reached by the Government.

The drug industry has welcomed this provision of the law, and has indicated satisfaction with its administration (83). A leading drug manufacturer has pointed out that, under the new drug section, the public has been given needed protection from irresponsible drug marketing without any hampering of free enterprise or drug discovery, and that a large majority of the industry would "recommend a head examination for any manufacturer who wanted to repeal the new drug provisions of the law at this late date." This manufacturer concluded:

"It is true that most of the big-name, full-line houses—houses like Lilly, Upjohn, Squibb, Abbot, and Parke, Davis, for example—had long maintained rigorous manufacturing controls, high-quality standards, large-scale pharmacological and clinical testing of new products, and other standards which the new drug section compelled the whole industry

to adopt. But there is no indication that the law has wrought hardship on any company, large or small, except perhaps for its desirable discouragement of fly-by-nighters who might otherwise have exploited and possibly endangered the public. On the contrary, the law has profited the whole industry to the extent that the public, including the medical profession, now takes for granted the purity and quality of all drugs on the market and their safety when used in accordance with labeled instructions." (84)

At present there are no provisions in the food chapter of the Federal Food, Drug, and Cosmetic Act comparable to the new drug section. Section 402 (a) (1) declares a food to be adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health. This provision places on the Government the burden of proving by a preponderance of the evidence, in a court of law, that a chemical added to food is harmful. In some instances, the Government does not possess the necessary proof of hazard, although doubt as to safety may exist. In other instances, the Government secures the necessary proof, but only after injury has occurred.

Thus, if a chemical is used on or incorporated into a food without adequate toxicity testing, as a practical matter the Government is frequently helpless and the consumer unprotected. If there is no evidence available as to the toxic nature of the substance, the Government cannot produce evidence in court to sustain its burden of proof. In such a situation, the Government may be compelled to undertake the burden of conducting chronic toxicity studies. Such experimental work may require years for completion. Meanwhile, the manufacturer may continue to market its product unmolested despite possible subtle damage to the health of the consumer.

A comparable situation could not exist under the new drug section. If evidence of safety was not generally available for a product which a drug manufacturer proposed to market, it would be a "new drug." The Federal Food, Drug, and Cosmetic Act defines a "new drug" as a drug "not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof." If such a product were shipped in interstate commerce, under existing law it could be seized wherever found and condemned in an appropriate United States district court. In a proceeding of this character, the Government would be required to prove only that the drug is not generally recognized as being safe for use and that no new drug application is in effect for it. The Government would not have the burden of establishing that the product was unsafe.

Under section 402 (a) (2) of the act, a food is deemed to be adulterated if it bears or contains any added poisonous or deleterious substance which is unsafe within the meaning of section 406. The latter section provides:

". . . any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice, shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Administrator shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a)."

The primary purpose of section 406 was to provide a means by which maximum residue tolerances on food could be established for needed pesticides so as to protect the public health. The

Food and Drug Administration has completed hearings to establish tolerances on a large number of pesticides, and regulations are now being formulated. But the setting of tolerances does not give the Food and Drug Administration any advance control over the use of pesticides. Unless the manufacturer conducts adequate chronic toxicity tests for a new pesticide, the Government is powerless to afford the consumer any protection until it completes its own toxicity tests and conducts a formal public hearing for the purpose of issuing tolerance regulations. Both procedures consume more time than is consistent with efficient protection of the public health.

The Federal Insecticide, Fungicide, and Rodenticide Act prohibits the adulteration and misbranding of pesticides sold in interstate commerce, and requires that a manufacturer of an economic poison register it with the Secretary of Agriculture before distributing it in interstate commerce. When registering a pesticide, the manufacturer is required to submit a complete copy of the labeling accompanying the economic poison and a statement of all claims to be made for it, including the directions for use. If requested by the Secretary, the registrant must supply a full description of the tests made and the results thereof upon which such claims are based. The Secretary may also require the formula to be submitted. However, the act requires that the Secretary register an economic poison even though he is not satisfied with the data submitted, if the manufacturer insists that he do so.

A representative of the Department of Agriculture testified that section 4 (a) (4) of that statute, which provides that the material filed in connection with the application for registration shall include, if requested, a full description of the tests made and the results thereof upon which the claims are based,

". . . does not sufficiently require that adequate tests be made and place the responsibility upon the applicant to prove the safety and effectiveness of his product. The law would be much stronger if the applicant was required, in those cases where the information was not otherwise available, to bear the burden of proof of the effectiveness and safety of his product for the uses intended. As a prerequisite to registration, he should be required to carry out adequate testing, both as to possible toxicity hazards and effectiveness, and include with the application a complete report of results of such tests." (85)

In discussing the "registration under protest" provision of the Insecticide Act, he pointed out:

"The provision for registration under protest has not, up to the present, caused difficulty insofar as toxic residues on foods are concerned. However, it is quite conceivable that a manufacturer might desire to apply an economic poison on food crops in a usage which was not considered safe and demand registration under protest, which would have to be granted. The law would be stronger if the provision for registration under protest were omitted and authority given to refuse registration unless it appeared to the Secretary that the composition of the article is such as to warrant the proposed claims for it and that the article and its labeling and other material required to be submitted comply with the requirements of section 3 of the act. Such authority should, of course, be properly safeguarded to prevent arbitrary or capricious action." (86)

Furthermore, the Insecticide Act does not require a manufacturer to furnish suitable methods of analysis for determination of residues on the food involved (87). Thus, while the Federal Food, Drug, and Cosmetic Act places upon the Food and Drug Administration the responsibility of safeguarding our food supply from poisonous and deleterious substances, an insecticide may be registered under the Insecticide Act, and enjoy widespread use, despite the fact that the Food and

Drug Administration, as well as the vitally concerned food canner and distributor, may have no method of determining the quantity of the economic poison which remains in or on the food.

Representatives of those who manufacture and sell pesticidal chemicals, and a number of entomologists, expressed the view that present legislation in this field is adequate to protect the public (88). Several favored what one witness admitted could be described as "the human guinea pig approach." This entomologist maintained that:

"The really significant test is to feed a considerable amount of naturally contaminated food to a numerous group of people, taking care to duplicate the technique used in testing a new drug, that is, starting with very small amounts and increasing until some effect is noticed or it is reasonably certain that none will develop. How can this be done? It is already being done in an unplanned way with every new agricultural chemical." (89)

Some of these witnesses also took the position that if existing pesticide legislation were changed in any manner, the result would impose a serious burden upon the farmer (90). Representatives of the farmer, however, do not appear to share this concern. The legislative counsel for the National Grange, the oldest national farm organization in the United States, testified that the development of new chemicals for use in or on foods had intensified and created new problems, and that the grange believed that changes were required in existing legislation in order to deal with these problems (91).

In commenting on the inadequacies of the Insecticide Act, the general counsel for the Grocery Manufacturers of America advised the committee:

"Now it is clear that this act is not an appropriate and adequate legislative remedy against the unsafe addition of a pesticidal residue on or in natural food which may be dangerous to the public health; for, in the first place, it is an economic law to aid the farmer rather than a health law to protect the consumer, and it is designed to regulate the agricultural use of poisonous pesticides in growing natural food which actually cause a toxic residue on or in it. In the second place, this act does not expressly provide a due control of such a toxic residue, and it is so loosely drawn that a manufacturer of a poisonous pesticide may operate under it without scientifically making the advance residue determinations which are necessary to protect both the consuming public and an affected food manufacturer. That must be so, because the public-health danger of a toxic pesticidal residue exists and has increased despite this act. And, in the third place, the unsafe addition of a pesticidal residue on or in natural food should be duly regulated by the FDC Act instead because it is our national food law to assure a safe use of food. That act now partly regulates a toxic pesticidal residue, as we have seen; and manifestly it should complete that regulation, to the extent this is required for the protection of public health." (92)

Section 401 of the Federal Food, Drug, and Cosmetic Act authorizes the Federal Security Administrator to define and standardize foods for the purpose of promoting honesty and fair dealing in the interest of consumers. This empowers him to determine whether a chemical proposed for use in a standardized food has been demonstrated to be safe. Hearings conducted by the Food and Drug Administration leading to the issuance of regulations defining and standardizing foods have been unduly protracted at times, because of the submission and consideration of conflicting testimony on the safety for use of some proposed optional ingredient. It would seem preferable that food standardization hearings should not be devoted to that type of question, but rather to the economic factors implicit in the criterion of "honesty and fair dealing in the interest of consumers."

A provision in the food chapter of the statute generally similar to the new drug section would help to prevent these burdensome delays in the promulgation of food standards.

More important is the fact that there are many food products on the market which are not, and may never be standardized. The Administrator has no advance control over the use of chemicals in an unstandardized food. This differs from the situation which exists in the case of meat products. The Federal Meat Inspection Act requires that a meat packer who is subject to the statute, and wishes to use a chemical, must first obtain the approval of the Meat Inspection Service of the United States Department of Agriculture. He is required to show, among other things, that the proposed chemical is harmless, and the burden of proving its freedom from toxicity is on him.

If, after reviewing the data submitted by the petitioner and all other available data, the Meat Inspection Service is convinced that the chemical is safe, permission to use it is granted; otherwise, it may not be employed in meat products. It is anomalous that certain chemical "emulsifiers" have not been permitted in such products but, as indicated, are widely used in many other foods. It is this general type of advance safety control exercised since 1906 over the use of chemicals in meat products that was proposed for other foods by many of the witnesses.

VII. Conclusions and Recommendations

The increasing use of chemical additives in the production, processing, preservation, and packaging of food has created a serious public-health problem. The evidence presented reveals that existing Federal laws do not provide complete protection to the public against the addition of chemicals which may be unsafe.

The strong recommendation of most of the witnesses before the committee was that no chemical should be permitted entry into the Nation's food supply until its safety for use has been demonstrated beyond a reasonable doubt. A provision in the law to that effect would benefit the food and chemical industries as well as the consuming public (93). Thus, the Director of the Bureau of Nutrition of the Department of Health of New York City told the committee:

"I would think that the industry, meaning the chemical industry or food industry in general, would welcome an outside authority, a nonprejudiced outside authority, to pass judgment upon the adequacy of safety tests that responsible members of industry itself use before they apply it to food. Certainly the chemists and scientists in these organizations can be put under tremenduous pressure by management and many of them, I am sure, would welcome the final judgment of an outside source whether or not the addition of a new chemical may or may not constitute a health hazard." (94)

In the committee's view, it is important that unnecessary obstacles to technological improvements in food production and processing not be created. It is believed that a "chemicals in food" amendment to the Federal Food, Drug, and Cosmetic Act would not hamper scientific improvement in this field, but rather would stimulate research, aid in technological improvement, and redound to the benefit of the food and chemical industries. It is interesting to observe, in this connection, that the New Drug Section has given new impetus to pharmaceutical research, and new strength to the ties between drug manufacturers and medical research facilities outside the industry (95).

It is clear that before a chemical is used in or on a food, or as a food, it should be subjected to acute and chronic toxicity testing to insure, as far as possible, that the public health will not

be endangered. It is not possible to delineate, in any legislation, the specific methods or conditions of testing which should be performed on any chemical or class of chemicals. The specific type and duration of tests necessary to insure the protection of the public health will vary, depending on the composition of the chemical and the food involved, the breakdown products of the chemical and food when brought into contact or intermingled, the metabolic fate of the chemical, the quantity of the chemical or related chemicals already found in the diet, and many other factors. For this reason, your committee recommends that legislation to cope with the chemicals in food problem should not attempt to specify the type and manner of pretesting which should be conducted. Rather, the legislation should provide that evidence that the chemical is safe, and does not produce harmful chemical reactions, in the end food product, should be submitted to the Food and Drug Administration for clearance before the chemical is utilized. In any evaluation of the safety of any proposed chemical, the extent of the use of the chemical, or similar chemicals, in or on other foods, must be taken into consideration.

It was suggested by some witnesses that any legislation should treat insecticides differently from chemicals which are added to a food product after harvesting. It was contended by these witnesses that insecticides are not deliberately added to foods as are most other chemicals used for food purposes, and that the amount of the insecticide remaining on the food is not a constant one, as may be the situation in the case of other chemicals. However, insecticides, as well as other chemicals used in the production and processing of food products, are deliberately rather than accidentally utilized to perform a specific function with regard to the food in question. It is true that it is not customarily intended that insecticides appear on the end food product, but under certain conditions, particularly when proper precautions are not taken, they may so appear, in greater or smaller quantity. It is little comfort to the consumer that the manufacturer or applier did not intend that the insecticide remain on the food product, or at least not in such great quantity.

It is essential that, before a pesticide is permitted to be used on a food, reliable methods of analysis for the quantitative determination of the chemical be available. Some insecticides were widely used before such information had been obtained, and insecticides are presently being employed for which such methods are not available. The importance of this requirement is obvious. If the quantity of chemical in or on the food cannot be ascertained, it cannot be determined whether or not any hazard is involved. However, only part of the question is answered when the quantity of the particular chemical in the diet is established. This information is meaningless unless the effect this quantity will have on the human body when ingested both for long and short periods of time, and by all segments of the population, is also known. The continued high level of health and vitality of our Nation demands that both of these questions be answered regarding any alien material which may find its way, in any amount, into our food supply.

Your committee recognizes the need for supplemental legislation which will provide more adequate protection to the public. While the committee is in agreement with the opinions expressed by many of the eminent witnesses who testified, that no chemical should be permitted in or on the Nation's food products until its safety for the use for which it is employed has been demonstrated beyond a reasonable doubt, it also recognizes the necessity for the continued use of chemicals in sprays and other insecticides if the Nation is to be supplied with food. In the committee's investigation, which included inspection of the facilities used in the production and processing of a number

of the items contributing to the food supply of this Nation, it has been convinced that with proper care, and by taking reasonable precautions, it is possible to utilize the poisonous properties of such chemicals in destroying insects and controlling diseases which attack many crops, without endangering the health of the people who consume these products. The committee does not believe that an insecticide which can be used without danger to the consuming public, and with benefit to the grower, should be kept from the market because of the failure of a few to observe the recommended directions for use.

In conclusion, the evidence has convinced your committee that chemicals have been utilized in and on the food supply of the Nation without adequate and sufficient testing of their possible long-range injurious effects; that the public is entitled to greater protection with respect to the foods it must necessarily consume; and that such protection is not afforded by existing legislation, under which the Government may take no action until after the food has been placed upon the market and injury may have occurred. Your committee recommends, therefore, that the Federal Food, Drug, and Cosmetic Act be amended to require that chemicals employed in or on foods be subjected to substantially the same safety requirements as now exist for new drugs and meat products. Adequate provisions for a comprehensive judicial review of administrative decisions should be included in such an amendment.

Respectfully submitted,

JAMES J. DELANEY, New York, *Chairman.*

E. H. HEDRICK, West Virginia.

PAUL C. JONES, Missouri.

A. L. MILLER, Nebraska.

GORDON L. MCDONOUGH, California.

REFERENCES

Citations are to representative references, and are not intended to reflect all supporting testimony. All reference citations indicate the committee hearing volume involved and the page numbers in that volume. The designation "1950" referes to the 878-page volume of the committee hearings held during 1950, entitled "Chemicals in Food Products, Hearings Before the House Select Committee To Investigate the Use of Chemicals in Food Products, Eighty-first Congress, Second Session." The designation "Part 1" refers to the 582-page volume of the hearings held during 1951, entitled "Chemicals in Food Products, Hearings Before the House Select Committee To Investigate the Use of Chemicals in Food Products, Eighty-second Congress, First Session, Part 1." The designation "Part 2" refers to the volume containing pages 583-1053 of the hearings held during 1951, entitled "Chemicals in Foods and Cosmetics, Hearings Before the House Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics, Eighty-second Congress, First Session, Part 2." The designation "Part 3" refers to the volume containing the hearings held during 1952, entitled "Chemicals in Foods and Cosmetics, Hearings Before the House Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics, Eighty-second Congress, Second Session, Part 3."

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Additional Views on the Use of Chemicals, Estrogenic Hormones, and Pesticides in the Production of Foods

We have hesitated to state some additional views on this subject. Our views are not in disagreement with the full report. We agree with the full report and have signed it. We did feel that because of the importance of these topics some additional thoughts in relation to chemicals, estrogenic hormones, and the use of pesticides in the production of foods would be in order.

CHEMICALS IN FOODS

The United States Food and Drug Administration reveals that there are now more than 700 chemicals used in some manner in the production of foods. This makes chemicals in foods a most important problem. Science has made great progress in the use of chemicals in foods. There are some 276 of these 700 chemicals that are being used, although their safety in the production and processing of foods has not been established to the satisfaction of the Food and Drug Administration. To us this presents a serious problem.

We believe that no chemical should be added in foods sold for human consumption until its safe addition has been adequately determined by appropriate scientific investigations. It does seem that the law should require the proper pretesting of any chemical to determine if it is harmful, before that chemical is added to the food supply. Unless this is done the consuming public is not being properly protected. The law of the land should safeguard the public health. Food must be safe for human consumption.

As we understand the present law, it does not require a pretesting of chemicals before their use in foods as it does for the use of drugs. While the act prohibits the addition of unsafe chemicals in foods, it does not set out in a clear way how this shall be done. The Administration writes certain definitions, composed in such a way as to exclude any unsafe additions.

The present law is defective, because a violation may not be disclosed until these foods have been sold or consumed in large quantities. The present enforcement under the law is a long procedure. The Government must prove the violation. In the meantime the consumer is left exposed to chemicals which might prove dangerous. The pretesting requirements should make certain that the addition of the chemical to the food is safe. The burden of proof as to the safety of the chemical should rest upon the industry.

We do feel that the food industry has been diligent in presenting foods which are safe, and they have carried on extensive experiments, cooperating with Government and health agencies to the end that the public will have protection. It is always the case, however, that during the stress of economic competition short cuts are frequently adopted which may put the consuming public in danger of chemicals being used that are not properly pretested or safe.

The law should be clarified and strengthened in order to protect the public from those concerns who seek short cuts in the production and processing of food that may be dangerous to the public. We are certain the food industry will cooperate 100 percent with Government agencies and the Congress in supplying an ever-increasing need for food which is safe for human consumption.

ESTROGENIC HORMONES IN FOOD

This is a new field. It may offer much hope in the production of meat. There are some dangers apparent which the public should understand.

The importance of producing chickens with the aid of estrogenic hormones is evidenced by the fact that more than 30 million chickens were treated with the hormone pellets last year. There are certain dangers which should be pointed out. The mink growers of Wisconsin and Illinois have a bill pending before Congress, asking for damages because they fed the heads of chickens to their mink; the chickens had been treated with the hormone pellet, the mink were sterile. Does the Government owe these mink growers damages because they followed the advice of the Agriculture Department and fed the heads which had a residue of the estrogenic hormones in the flesh?

In our opinion there has not been sufficient study to permit the indiscriminate use of estrogenic hormones in the production of meat. It seems quite possible that chickens and other meat which has been treated with the hormones should be so labeled when offered for sale to the public. We are convinced that there are dangers in eating the heads of chickens, the livers, and other products, because they might contain excessive amounts of hormones which would be harmful. The individual cannot buy hormones without a prescription from a physician. It is possible for chicken producers and others

to buy these pellets without any restrictions from drug houses.

The problem requires more study. We would not want to place any blocks in the way of progress, because this brand new field may prove to be a valuable one when it comes to the production of meat. It may well reflect to the benefit of agriculture and the consuming public. It does seem that additional experiments need to be done before the green light is given to the widespread use of these estrogenic hormones.

PESTICIDES

More than 30,000 formulas have been registered with the Department of Agriculture for use in the battle between man and insects. The chemical industry has produced these new and powerful insecticides to cope with the problem of protecting the food supply of the Nation. Many of these pesticides are extremely toxic. Our concern is with the fact that the housewife frequently fails to realize that insecticides such as DDT, chlorodane, selenium, and many others in combinations, which can be bought over the counter, are deadly poison and must be used with extreme caution. When these pesticides are used upon fruits and vegetables, these crops should be thoroughly washed before they are used. In fact we doubt very much if some of these new, powerful insecticides should be authorized for private home use on growing garden and fruit crops.

There was a time when the widespread use of DDT was urged on dairy farms. Today we realize that DDT is stored up in the fat and is a poison.

The commercial producers of these pesticides are doing an excellent job and are cooperating in every way with Government and health agencies in the protection of the public. The laws may be sufficient to protect food in interstate commerce. Much of the food used on the family table is produced in the garden at home. It is this important segment of food consumers which should be given every assistance and direction in the use of the many pesticides now available on the market. The careless, indiscriminate use may cause chronic illness to the family. We are convinced the public has not been properly alerted as to the dangers from the improper use of these pesticides. The individual may not die from their use, but he becomes ill; and there can be serious damage to the liver, kidney, and other vital organs. We believe the toxic insecticides, like chlorodane, selenium, and others of similar toxic nature, should not be offered to the public for use without proper controls.

There are also certain sprays that the housewife uses around the house which are extremely toxic. The public often feels that because something can be bought over the counter it must be safe. There are many dangers connected with the improper use of sprays around the house.

In presenting these additional views we do not want to be an alarmist, because in our opinion it would not be possible to produce the fruits and vegetables we now produce or to control insects unless some of the new and powerful insecticides were used. We believe the large industries which manufacture these insecticides and the food industry which must use the insecticides are using every effort possible and cooperating in every way with Government and public-health officials in seeing that no residue of the poison remains upon a food offered to the public for consumption. The great danger lies in the careless use of these sprays and insecticides by the general public upon their home gardens.

The general public needs more education and should be alerted at all times to the dangers when they are using some of these powerful new sprays and insecticides.

A. L. Miller.

Gordon L. McDonough.

Additional Views of Congressman Gordon L. McDonough

The rigid requirements of the State of California to protect the public by requiring the label on all insecticides and pesticides, to carry the name of the poison and the amount, together with the antidote for such poison, and also the rigid inspection of fruits, vegetables, and flowers on which they are used, are recognized as one of the best State regulations to protect the public and the workmen engaged in the agricultural industry against serious industrial hazards.

GORDON L. MCDONOUGH.

MINORITY VIEWS

It is with great reluctance that I find it necessary to write this minority report. I have tried to make my views and my position completely clear not only to the counsel and staff of the Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics but also to the members of the committee.

Subsequent to my original criticisms of the report of June 25, some changes were made in the proposed report. However, in my opinion the changes have been inconsequential and do not meet my objections.

On Monday, June 30, 1952, I met with the counsel of the committee, Mr. Kleinfeld and Mr. Gottlieb, and two members of the committee in an attempt to point out some of the deficiencies in the report as revised.

Since no agreement was reached, I feel it is my duty to make my views quite clear in a minority report.

The whole essence of my objections to the report submitted to me by counsel for our committee is that the report is "alarmist" in nature. It would, in my opinion, contribute to the difficulties of our producers of foodstuffs in the United States and yet add nothing of assurance to the consuming public.

This is a matter of grave concern.

Since 1946, according to the Food and Agriculture Organization of the United Nations, the world population has increased 12 percent, while world food production has increased but 9 percent. There is real foundation for the statement that actually man is breeding and eating himself out of house and home. There is real foundation for the FAO's estimate that half of the world's 2,400,000,000 population exists on a near-starvation diet. It is in the light of these facts that I protest a nonconstructive approach to any discussion of the use of chemicals in foodstuffs at this time.

Even in our own Nation, which is the best fed in the world, we face the possibility of a food shortage within the next 23 years. Today, on an estimated 462 million productive acres, we are feeding our population of 155 million. Yet, like the rest of the world, our population, too, is increasing at the rate of nearly 2½ million persons a year. By the year 1975 our population by conservative estimates will be 190 million persons. To serve our consuming public with today's menu will require an additional 115 million acres.

Only some 45 million acres by conservative estimate appears possible as an increase through reclamation, drainage, and other processes. We stand the chance of being 70 million acres short of that required to feed our own population. To overcome this means that we must employ every safe advantage of benefit to be gained by science in the conservation or maintenance of our fertile acres in the proper use of every new soil-building and plant-food-producing chemical and in the wise and safe use of every conservative pesticide that will protect our crops in the future from the invasions of pests and insects.

I am convinced that the majority report as presently constituted adds nothing in this direction and therefore I cannot be a party to it. I feel very strongly that the report is reactionary and a deterrent to needed progress.

While parts I and II of the report as submitted to me on June 25 and unchanged in later presentations are subject with one exception, later referred to in my conclusions, to my endorsement, I find part III to be fraught with inequities and inaccuracies. To my mind, it does but little good to discuss, as is done in the beginning of part III, seven chemicals which are by today's legal procedures denied access to interstate commerce. Far better to have mentioned those seven chemicals by name and to have assured the consuming and producing public of the efficiencies of our tax-supported agencies which have succeeded in denying these chemicals the privilege of interstate commerce.

And, again, in part IV, the report indicates that selenium may be used as an agricultural insecticide. Selenium has been registered by the Department of Agriculture under the Insecticide Act of 1947 for only one crop use and for use on ornamentals and certain greenhouse purposes. It has not been registered for use on any other food crop and its sale for use on any other food crop would be illegal and the product could be seized under existing law. Selenium is not permitted on apples and the indirect reference to its use thereon is not only unfair—it is destructive.

It is one thing to raise an alarm; it is another thing to put out the fire.

Again, in the discussions of the use of chemical emulsifiers used in a wide range of foods, as it appears in part III and again is enlarged upon in part V of the report, it should be borne in mind that the harmful toxicity of emulsifiers has never been proven.

The burden of testimony would lead one to the conclusion that they are nontoxic and therefore any discussion of them is economic rather than a question of the effect of the health of individuals.

With reference to the use of hormones in food production, I think it only fair to point out that in part III the statement is made:

"Examination showed that 60 percent of the sampled chickens contained portions of unabsorbed stilbestrol pellets in areas of the neck which would remain with the consumer after normal servering of the head from the carcass. Prompt legal action followed, and approximately 50,000 pounds of stilbestrol-treated chickens were seized and *condemned.* [Italics mine.]"

I call your attention to the word "condemned."

Actually this statement appears to be based upon the testimony of Charles A. Herrmann, chief, New York district, United States Food and Drug Administration, New York, N. Y., testifying before the select committee on January 14. Mr. Herrmann testified on page 1291 of part 3 of the hearings, as follows:

"Altogether we took seizure action against 13 lots, aggregating 792 crates, or 60,000 pounds, with a wholesale value of approximately $25,000. The seized lots originated with seven different shippers respectively in Maine, New Hampshire, Connecticut, North Carolina, and Pennsylvania. . . .

"Following seizure, claims were filed in each instance, and, in condemnation decrees protected by adequate bond, salvage was permitted under the immediate supervision of an inspector of the Food and Drug Administration. The salvage consisted of the removal of the entire necks at the shoulders and further evisceration of each bird. The necks so removed were denatured with Lysol and moved to a fat-rendering plant. On completion of this process *the edible portion of the bird was released for the market.* [Italics mine.]"

The basis of my minority report is that adequate legal processes are already in existence for the full protection of the consuming public.

Again, despite the fact that the Food and Drug Administration in this instance permitted these seized birds to reach the market, the committee is expected to recommend: "The committee is of the opinion that poultry or other animals which have been chemically treated be labeled so as to reveal that fact, and that restaurants serving such chemically treated food be required to advise customers to that effect."

It seems to me that before legislation requiring this be entered into that the full import of all the facts be had. Certainly a conclusion upon which to base such a recommendation is not borne out by the testimony before the select committee. Nor would such a recommendation protect the consumer. No more cumbersome a regulation could be imagined.

Regarding pesticides, I have no disagreement with the general remarks of the report until the paragraph in the report beginning:

"In 1948 the Council on Foods and Nutrition of the American Medical Association declared that the appearance of the new insecticides had created a danger; that there was an appalling lack of factual data concerning the effect of these substances when ingested with food; and that the chronic toxicity to man of most of the newer insecticides was entirely unexplored. Subsequently, on January 28, 1950, the Council on Foods and Nutrition issued a statement which declared in part:

'The introduction of numerous synthetic organic pesticides offers promise for increasing the Nation's food supply and improving health through the control of insects and other pests. Past experience, however, indicates that poisons cannot be used safely on food crops without the development of certain fundamental knowledge concerning the poisons. What these materials will do to pests and food crops and to workers who handle them must be known, and there must be developed, also, a knowledge of what these materials will do to warm-blooded animals and man when small amounts of residue are incorporated in their foods. Furthermore, practical methods of analysis should be available to permit identification and measurement of residues that may persist on or in consumer products. Such essential information is undeveloped for many of the agricultural poisons now in use.'"

This paragraph, a quotation from a 1950 report, no longer is completely true because of additional information now available. This lack of specific knowledge regarding the effects of these chemicals on pests, food crops, and the consumer early was recognized by the Department of Agriculture and the Public Health Service. Both of these agencies have been working intensely on this problem with the result that today we do know a great deal about what these chemicals do to pests, something regarding their effects on crops, and considerable about the fate and toxicity in man. Moreover, we now have practical methods of analysis for most of these chemicals.

The Public Health Service for years has been studying the toxic effects of many of these chemicals on man. Recently their studies on the toxicity of pesticides at Wenatchee, Wash., Savannah, Ga., and in the various Public Health Service Hospitals have failed to show a single case of chronic poisoning due to residue of pesticides chemicals in foods. As new pesticides are developed, much research is needed to establish their toxicity for man and the Public Health Service should be adequately supported in these essential studies.

The following was read by counsel when he was interviewing Dr. Fred Bishop of the Bureau of Entomology, United States Department of Agriculture:

"The Council on Foods and Nutrition of the American Medical Association is acutely aware of the toxicological problems presented by the rapid introduction of synthetic organic pesticides

and herbicides. The chemical contamination of foods with residues of these substances is but a part of the broader problem created by their wide use, for in addition to the danger from ingestion, the effects of inhalation and skin absorption must be determined.

"The problem is created by the great number of new pesticides on the market. The appearance of these is creating an increasing volume of inquires at association headquarters. That danger exists is evidenced by the appalling lack of factual data concerning the effect of these substances when ingested with food. The chronic toxicity to man of most of the newer insecticides is entirely unexplored. In fact, the majority are so new that their limitations and even their full scope of usefulness have not been established."

The counsel for the committee following the reading of the quotation asked Dr. Bishop:

"Do you agree with that statement, sir?"

Dr. Bishop replied:

"I believe that is an editorial and a generalized statement, and I cannot agree with it. 'Entirely unexplored', I don't believe that anybody else would agree with that either. I am rather surprised that a statement would appear in that journal as sweeping as that."

I feel that, by their very nature, pesticides should be considered separate from other chemical additives for the following reasons:

1. Pesticides are necessary and must be used to produce food products and to protect the public health. Their use is from necessity and not by choice. These chemicals are present in varying and minute amounts.

2. Pesticides are already controlled by a legislative pattern consisting of Federal and State laws and regulations thereunder. These laws are the Federal Insecticide, Fungicide, and Rodenticide Act of 1947, the Food, Drug, and Cosmetic Act of 1938, State laws in 39 States which in general follow the pattern of the Federal Act of 1947.

The Federal Insecticide, Fungicide, and Rodenticide Act of 1947 requires that before a pesticide can be shipped in interstate commerce, it must be accepted for registration by the United States Department of Agriculture. Registration depends upon a showing that the product is both safe and efficacious for the purposes for which it is to be sold. Supporting data must be made available to the Department before registration is granted. Lack of data will result in a refusal to register. The type of supporting data depending upon the claims made consist of: entomological efficiency, pathological toxicity, residue at harvest, acute and chronic toxicity data, data showing effect on soils, data showing effect on taste and flavor. The solicitor for the Department of Agriculture has ruled that under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947, necessary data can be required before registration to show that the material is not only efficacious for the uses recommended but that it is safe when used as directed to the spray operator and to the consuming public.

The Food, Drug, and Cosmetic Act directs the Federal Security Administrator to limit, by regulation, the quantity of added poisonous and deleterious materials, including pesticides, which remain on any food "to such extent as he finds necessary for the protection of public health."

Standard procedure under existing laws before a product is registered is that the United States Department of Agriculture consults with the Food and Drug Administration and the United States Public Health Service. Both of these agencies are fully informed before a product can be sold in interstate commerce and the product is not accepted for registration if, in the opinion of any

one of those agencies, it would be detrimental to the public health.

Under the State laws, similar controls and authority can be exercised at the State level.

Continued investigation of all phases of the product such as entomological efficiency, pathological toxicity, flavor and taste, effects on soil are continued by the industry, by the United States Department of Agriculture, Bureau of Entomology and Plant Quarantine, Bureau of Plant Industry, State land-grant colleges, the United States Public Health Service, Food and Drug Administration, and the Fish and Wildlife Service. The claims under which the material is registered are reviewed at regular intervals by the Department of Agriculture in the light of any new research data.

It is common practice in the fresh fruit and vegetable industry to wash products after harvest before shipment. This is because the Food and Drug Administration polices all shipments in interstate commerce. This applies to practically every fresh fruit and vegetable. Investment in washing machinery is one of the heaviest capital items in the fresh fruit and vegetable producing, and shipping business. Use of such equipment insures the removal of spray residue. In addition, washing fresh fruits and vegetables in preparation for retail sale is a growing practice. Thus, washing at both wholesale and retail levels affords protection against the presence of toxic residues. Authority now exists under Federal and State laws to bar from commerce any fresh fruit and vegetable product containing toxic residues which might be injurious to health.

In California, for example, under standards set by State law, 2,363 samples of produce were analyzed in 1949 and only 110 were found to contain spray residue in excess of State tolerances. Of course, it should be borne in mind that "tolerances" always err in favor of assurances to the consumer. In 1950, 2,842 samples were analyzed and 103 were found to contain overtolerance amounts; however, the averages and circumstances involved in these cases did not warrant filing criminal complaints. California imports some fruits and vegetables from other States and countries. Analyses of fruits from Oregon, Washington, and Idaho, and of vegetables from Florida, Texas, Arizona, and Mexico during 1950, did not reveal any deleterious residues in excess of legal tolerances.

The chemical industry, in developing a new pesticide, first screens thousands of chemicals to determine their biological efficiency. If one of the chemicals shows promise, research is started on its efficacy for pest control and toxicological research is immediately started to determine its practicability for use. The toxicological and biological research is started by the producing company. When promise is shown, work is expanded in cooperation with private research institutions, the United States Department of Agriculture, and land-grant colleges. The Food and Drug Administration and the United States Public Health Service are consulted. A recent survey of the industry shows that the cost of research before a product can be registered for sale ranges from $200,000 to $400,000.

The Food, Drug, and Cosmetic Act of 1938 has given the Food and Drug Administration full authority to protect the public from any residue hazards from the use of pesticides through the establishment of tolerances. Since 1938 only one official tolerance has been established, namely, on fluorine. In spite of the fact that tolerance hearings have been held on all of the principal pesticides at which 25,000 pages of technical data on residues and toxicity were presented, the residue tolerance hearings were closed on September 15, 1950, nearly 2 years ago, but no tolerances have yet been issued. Data upon every one of the pesticides referred to in section IV of the committee report were

included. The control called for does not await new legislaton but administrative action according to the existing law.

In the light of these facts, it seems unfair to me to state in part II that there are 276 chemicals being used in foods today, the safety of which has not been established.

This point is again referred to in part VI of the committee report as a basis for new legislation. I feel that the public is entitled to the exact status of the situation.

If any of these are pesticides, why have the regulations provided for in existing law not been forthcoming in this period of time? As not few (as indicated on p. 20 of the committee's report) but many witnesses testified, we should look to better use of authority already provided before concluding that additional authority is needed or could be wisely exercised if granted. In this light the total import of part VI of the report is in contradiction with the burden of testimony from witnesses closest to the subject.

In the final analysis we must designate to some responsible Government agency the determination of that which is or is not deleterious to the public health. We must recognize existing facilities which allow for the licensing of pesticides. Then, having arrived at that point, we must designate the policing agency to maintain a protective procedure so that our consuming public may be assured that what they consume is safe.

In the Public Health Service, the Department of Agriculture, and the Food and Drug Administration we have responsible agencies. Failure on the part of Congress to recognize their abilities to contribute to orderly progress is a sin of omission we must avoid. Failure in this committee's report to point out, at every turn, the good work of these agencies can leave but a negative conclusion with everyone.

We need faith in Government. We need both a feeling of security and encouragement in the hearts of our producers. We should assure the security of the consumer. Our Government is doing that. Let us admit it.

WALT HORAN.

[Note: Thomas G. Abernethy filed a minority report on July 5, 1952, wherein he concurred in the foregoing minority views of Mr. Horan.]

In the Food and Drug Administration

Report of July 25, 1952.—Seizures of 35 carloads of "pink wheat" contaminated with a poisonous mercury compound were approved in June and July, the Food and Drug Administration has announced. The wheat had been treated for seed, and later mixed with good wheat and shipped for food use when weather conditions prevented farmers from planting as much as planned. The pink color was derived from the chemical compound.

Wheat is inspected in freight cars and, therefore, any lots containing the poison can be readily detected before they are used in making either human or animal food products. The seizures, totaling about three-and-one-half million pounds, were made in Duluth, Minneapolis and St. Cloud, Minnesota, and in Seattle, Washington.

June was the first month of enforcement of the Federal Food, Drug, and Cosmetic Act of 1938 when the volume of food seized because of contamination with a poisonous chemical exceeded that of filthy and decomposed items, which annually account for 70 to 80 per cent of all food seizures.

In June, 657,298 pounds of filthy and decomposed foods were removed from interstate channels in 44 seizure actions. Largest in volume were nearly 200,000 pounds of sugar which had become defiled by insects and rodents during storage, and 139,616 pounds of decomposed frozen strawberries in 32-pound cans. For the month, food seizures totaled 72, drugs and dietary items 24, and devices five.

In a criminal action, a retail druggist of Washington, D. C., was convicted of substituting vitamin tablets for cortisone in at least five prescriptions he had filled. The case was developed after a physician reported to the Administration that two patients had not responded to the cortisone he had prescribed, and his tests established that they were not receiving cortisone. Judge Bolitha J. Laws fined the druggist $500, sentenced him to a year in jail—which sentence was suspended—and placed him on probation for one year.

Prescription Drug Regulations.—[Published in Federal Register July 25, 1952; 17 F. R. 6818]

TITLE 21—FOOD AND DRUGS

CHAPTER I—FOOD AND DRUG ADMINISTRATION, FEDERAL SECURITY AGENCY

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

DRUGS AND DEVICES; DIRECTIONS FOR USE; EXEMPTION FROM PRESCRIPTION REQUIREMENTS

Final Order

By virtue of the authority vested in the Federal Security Administrator by the provisions of sections 502 (f), 503 (b), and 701 (a) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1051, 1055; 65 Stat. 648; 21 U. S. C. 352 (f), 353 (b), 371 (a)), and after having considered all written comments filed with respect to the notice of proposed rule making published in the FEDERAL REGISTER on February 5, 1952 (17 F. R. 1130), the following regulations are promulgated.

1. Section 1.106 is revoked and a new § 1.106 is added to read as follows:

§ 1.106 *Drugs and devices; directions for use.* (a) "Adequate directions for use" means directions under which the layman can use a drug or device safely for the purpose for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(2) Quantity of dose (including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions).

(3) Frequency of administration or application.

(4) Duration of administration or application.

(5) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(6) Route or method of administration or application.

(7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

(b) *Exemption for prescription drugs.* A drug subject to the requirements of section 503 (b) (1) of the act, as amended by 65 Stat. 648, shall be exempt from section 502 (f) (1) if all the following conditions are met:

(1) The drug is:

(i) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or

(ii) In the possession of a retail, hospital, or clinic pharmacy, or a public-health agency, regularly and lawfully engaged in dispensing prescription drugs;

and is to be dispensed in accordance with section 503 (b), as amended.

(2) The label of the drug bears:

(i) The statement "Caution: Federal law prohibits dispensing without prescription"; and

(ii) The recommended or usual dosage; and

(iii) The route of administration, if it is not for oral use; and

(iv) If it is fabricated from two or more ingredients and is not designated conspicuously by a name recognized in an official compendium, the quantity or proportion of each active ingredient, and if it is not for oral use the names of all other ingredients.

Provided, however, That the information referred to in subdivisions (ii), (iii), and (iv) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed, and, in the case of ampuls too small or otherwise unable to accommodate a label but which are packaged in a container from which they are withdrawn for dispensing or use, the information referred to in subdivision (i) of this subparagraph may be placed on the outside container only.

(3) The labeling of the drug (which may include brochures readily available to licensed practitioners) bears information as to the use of the drug by practitioners licensed by law to administer it: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to administer the drug.

(c) *Exemption for veterinary use.* A drug intended solely for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The drug is in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice.

(2) The label of the drug bears:

(i) The statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian"; and

(ii) The recommended or usual dosage; and

(iii) The route of administration, if it is not for oral use; and

(iv) The quantity or proportion of each active ingredient if it is fabricated from two or more ingredients and is not designated conspicuously by a name recognized in an official compendium. *Provided, however,* That the information referred to in subdivisions (ii), (iii), and (iv) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed.

(3) The labeling of the drug (which may include brochures readily available

to licensed veterinarians) bears information as to use of the drug by licensed veterinarians: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among veterinarians licensed by law to administer such drug.

(d) *Exemption for prescription devices.* A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The device is in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device and is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(2) The label of the device (other than surgical instruments) bears:

(i) The statement "Caution: Federal law restricts this device to sale by or on the order of a ....," the blank to be filled with the word "physician," or "dentist," or "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(ii) The method of its application or use.

(3) The labeling of the device (which may include brochures readily available to licensed practitioners) bears information as to the use of the device by practitioners licensed by law to use it or direct its use: *Provided, however,* That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to use or order the use of such device.

(e) *Exemptions for drugs and devices shipped directly to licensed practitioners, hospitals, clinics, or public-health agencies for professional use.* Except as provided in paragraph (g) of this section, a drug or device shipped directly to or in the possession of a practitioner licensed by law to administer the drug or to use or direct the use of the device, or shipped directly to or in the possession of a hospital, clinic, or public-health agency, for use in the professional practice of such a licensed practitioner, shall be exempt from section 502 (f) (1) of the act if it meets the conditions of paragraphs (b) (2) and (3), (c) (2) and (3), or (d) (2) and (3) of this section.

(f) *Retail exemption for veterinary drugs and prescription devices.* A drug or device subject to paragraph (c) or (d) of this section shall be exempt at the time of delivery to the ultimate purchaser or user from section 502 (f) (1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

(g) *Exemption for new drugs.* A new drug shall be exempt from section 502 (f) (1) of the act:

(1) To the extent to which such exemption is claimed in an effective application with respect to such drug under section 505 of the act; or

(2) If no application under section 505 of the act is effective with respect to such drug but it complies with section 505 (i) and regulations thereunder. No exemption shall apply to any other drug which would be a new drug if its labeling bore representations for its intended uses.

(h) *Exemption for drugs or devices when directions are commonly known.* A drug or device shall be exempt from section 502 (f) (1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual.

(i) *Exemptions for inactive ingredients.* A harmless drug that is ordinarily used as an inactive ingredient, such as a coloring, emulsifier, excipient, flavoring, lubricant, preservative, or solvent, in the preparation of other drugs shall be exempt from section 502 (f) (1) of the act. This exemption shall not apply to any substance intended for a use which results in the preparation of a new drug, unless an effective new-drug application provides for such use.

(j) *Exemption for diagnostic reagents.* A drug intended solely for use in the professional diagnosis of disease and which is generally recognized by qualified experts as useful for that purpose shall be exempt, from section 502 (f) (1) of the act if its label bears the statement "Diagnostic reagent—For professional use only."

(k) *Exemption for prescription chemicals and other prescription components.* A drug prepared, packaged, and primarily sold as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions or for dispensing in dosage unit form upon prescriptions shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The drug is an official liquid acid or official liquid alkali, or is not a liquid solution, emulsion, suspension, tablet, capsule, or other dosage unit form; and

(2) The label of the drug bears:

(i) The statement "For prescription compounding"; and

(ii) If in substantially all dosage forms in which it may be dispensed it is subject to section 503 (b) (1) of the act, the statement "Caution: Federal law prohibits dispensing without prescription"; or

(iii) If it is not subject to section 503 (b) (1) of the act and is by custom among retail pharmacists sold in or from the interstate package for use by consumers, "adequate directions for use" in the conditions for which it is so sold.

Provided, however, That the information referred to in subdivision (iii) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed.

(3) This exemption shall not apply to any substance intended for use in compounding which results in a new drug, unless an effective new-drug application covers such use of the drug in compounding prescriptions.

(l) *Exemption for processing, repacking, or manufacture.* A drug in a bulk package (except tablets, capsules, or other dosage unit forms) or a device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt from section 502 (f) (1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking"; and, if in substantially all dosage forms in which it may be dispensed it is subject to section 503 (b) (1), the statement "Caution: Federal law prohibits dispensing without prescription." This exemption and the exemption under paragraph (k) of this section may be claimed for the same article. But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:

(1) An effective new-drug application held by the person preparing the dosage form or drug for dispensing covers the production and delivery to him of such substance; or

(2) If no application is effective with respect to such new drug, the label statement "Caution: For manufacturing, processing, or repacking" is immediately supplemented by the words "in the preparation of a new drug limited

by Federal law to investigational use," and the delivery is made for use only in the manufacture of such new drug limited to investigational use as provided in § 1.114.

(m) *Exemption for drugs and devices for use in teaching, research, and analysis.* A drug or device subject to paragraph (b), (c), or (d) of this section shall be exempt from section 502 (f) (1) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use; or engaged in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, research, analysis, or testing.

(n) *Expiration of exemptions.* (1) If a shipment or delivery, or any part thereof, of a drug or device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to that shipment or delivery or part thereof, at the beginning of such shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such drug or device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

(2) The exemptions conferred by paragraphs (i), (j) (k), (l), and (m) of this section shall continue until the drugs or devices are used for the purposes for which they are exempted, or until they are relabeled to comply with section 502 (f) (1) of the act. If, however, the drug is converted, compounded, or manufactured into a dosage form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the dosage form is labeled as required by section 503 (b) of the act and paragraph (b), (c), or (d) of this section.

(o) *"Intended uses."* These words in paragraphs (a), (g), (i), (j), (k), and (l) of this section refer to the objective intent of the persons legally responsible for the labeling of drugs and devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstance that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug or device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

2. A new § 1.108 is added, to read as follows:

§ 1.108 *Exemption from prescription requirements.* (a) The prescription-dispensing requirements of section 503 (b) (1) (A) of the act are not necessary for the protection of the public health with respect to the following drugs subject to section 502 (d):

(1) Exempt narcotic preparations described in 26 CFR 151.2 and sold as required by 26 CFR 151.180 through 151.185a.

(2) Drugs containing chlorobutanol, intended for external use only.

(3) Epinephrine solution, 1 percent, preserved with chlorobutanol and intended for use solely as a spray.

(4) Drugs containing one or more of the derivatives of barbituric acid and in addition a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of barbiturate derivative to cause a hypnotic or somnifacient effect.

Effective date. These regulations shall be effective upon the date of publication of this final order in the FEDERAL REGISTER, except the requirements of § 1.106 (b) (2) (ii), (iii), and (iv), (c) (2), and (k) (2) (iii), which shall be effective on August 1, 1953. Action taken in reliance upon the tentative regulations after April 26, 1952, and before this final order issued will be regarded as in compliance with the law.

(Secs. 502 (f), 503 (b), 701 (a), 52 Stat. 1050, 1051, 1055; 65 Stat. 648; 21 U. S. C. 352 (f), 353 (b), 371 (a))

Dated: July 22, 1952.

JOHN L. THURSTON,
Acting Administrator.

[F. R. Doc. 52-8156; Filed July 24, 1952; 8:51 a. m.]

ERRATA:

The title and the first sentence in § 1.106 (o) should be changed to read as follows:

(o) *Intended uses.* The words "intended uses" or words of similar import in paragraphs * * *

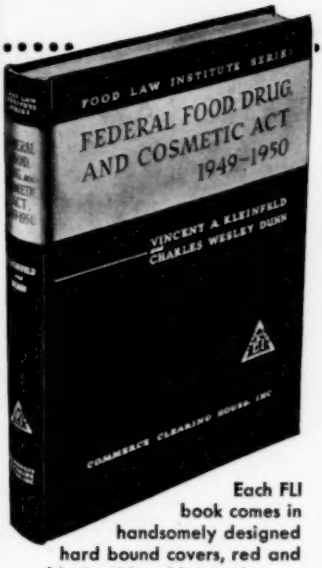
In § 1.108, "(a)" is omitted before the section title, and subparagraphs (1) through (4) are renumbered as (a), (b), (c), and (d).

In the Courts

Who's Exclusive?—Plaintiff agreed to sell its margarine to defendant exclusively in Dallas and adjacent territory. In an action against the defendant distributor for the balance of an account allegedly due, plaintiff was met with defenses that, as a foreign corporation, it was conducting intrastate business without a permit and hence was not entitled to sue in the courts of the state; and that the agreement entered into violated the state antitrust laws, and the debt, being in consequence of the illegal agreement, was unenforceable. On appeal from a judgment for the plaintiff the court held that since there was no agreement that the defendant's sales had to be restricted to plaintiff's products; since the plaintiff had many distributors outside of Dallas and its suburban districts; and since the agreement on the part of the plaintiff was found to have been consumated through its home office in Cincinnati, the transaction reflected was an interstate one and if offensive at all then only to the federal antitrust laws.

The conclusions of law were not affected, on rehearing, by the facts that the vice-president of plaintiff corporation confirmed the exclusive dealership arrangement in Dallas and that an employee of plaintiff lived in Dallas and answered correspondence. The court relied on a statement in the appellant's brief that said that the initial agreement was "subject to approval by the Home Office."

The issue of whether the plaintiff had violated the agreement by transferring the exclusive dealership agreement prior to notifying the defendant of such transfer and before selling defendant another large bill of goods was remanded for trial.—*Archie Sloan v. Miami Margarine Company*, CCH TRADE REGULATION REPORTS ¶ 67,323 (Texas Court of Civil Appeals, January 18, 1952, and February 22, 1952).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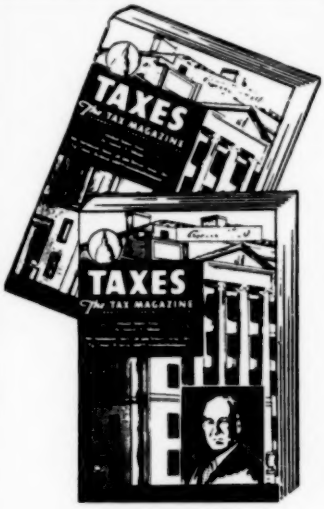

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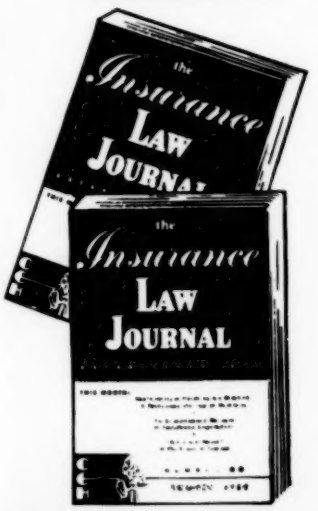

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